BS EN ISO 80601-2-56:2012

BSI Standards Publication

Medical electrical equipment

Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-56:2012. It is identical to ISO 80601-2-56:2009. It supersedes BS EN 12470-3:2000+A1:2009, BS EN 12470-4:2000+A1:2009 and BS EN 12470-5:2003 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/205, Non-active medical devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 77392 1

ICS 11.040.55

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2012.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-56

October 2012

ICS 11.040.55

Supersedes EN 12470-3:2000+A1:2009, EN 12470-4:2000+A1:2009, EN 12470-5:2003

English Version

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des thermomètres médicaux pour mesurer la température de corps (ISO 80601-2-56:2009)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2009)

This European Standard was approved by CEN on 16 September 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 80601-2-56:2012: E

Foreword

The text of ISO 80601-2-56:2009 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO 80601-2-56:2012 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by October 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12470-4:2000+A1:2009, EN 12470-5:2003, EN 12470-3:2000+A1:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-56:2009 has been approved by CEN as a EN ISO 80601-2-56:2012 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed.
201.11	7.3	Only the part of the first sentence relating to design is addressed.
201.7.9.2.14.101	7.5	Only the third paragraph of ER 7.5 is addressed.
201.11, 201.103	7.6	
201.11	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137.
201.7.2.1.101	8.7	
201.4, 201.4.2.101, 201.7, 201.7.9.2.101 e), 201.16, 201.101.1, 201.102.1, 201.103, 201.103.2	9.1	
201.9, 201.12.1.101, 201.12.2, 201.15, 202	9.2	The 4th indent of ER 9.2 is not addressed.
201.11, 201.13	9.3	
201.7.9.2.101 d), 201.12, 201.101, 201.102, 201.103	10.1	
201.12.2	10.2	
201.7	10.3	

Table ZA.1 (*continued*)

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
202	11.3.1	
201.14	12.1	
201.14	12.1 a)	
201.12	12.4	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.11, 201.15	12.7.4	
201.11, 201.15	12.7.5	
201.7, 201.12.2, 201.15, 206	12.9	
201.7, 201.7.2.1, 201.7.2.1.101, 201.7.2.2, 201.7.9	13.1	The requirement for information on the sales packaging is not addressed.
201.7, 201.7.2.1, 201.8, 201.9	13.2	
201.7, 201.7.9.1	13.3 a)	
201.7, 201.7.2.1.101 b)	13.3 b)	
201.7.2.1.101 c)	13.3 c)	
201.7	13.3 d)	This ER is only covered if the batch number is preceded by the word LOT.
201.7.2.1.101 d)	13.3 e)	
201.7.2.1.101, 201.7.2.1.101 e)	13.3 f)	
201.7, 201.7.2.1.101 f)	13.3 i)	
201.7	13.3 j)	
201.7	13.3 k)	
201.7.2.1.101 c)	13.3 m)	Presumption of conformity is only provided if symbols 4 to 7 are utilized.
201.7, 201.7.9.1, 201.16	13.6 a)	
201.7.9.2.101 c), 201.7.9.2.101 d)	13.6 b)	
201.7, 201.7.9.2.101 e), 201.16	13.6 c)	
201.7, 201.7.9.2.101 g), 201.16	13.6 d)	
201.7, 201.16	13.6 f)	
201.7, 201.7.2.9.2.101 j), 201.11, 201.16	13.6 h)	The requirement for information on the packaging is not addressed.

Table ZA.1 (*continued*)

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7	13.6 i)	
201.7.2.9.2.101 i)	13.6 n)	
201.7.2.9.2.101 d)	13.6 p)	
201.7.2.9.2.101 k)	13.6 q)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword v

Introduction vi

201.1 * Scope, object and related standards 1
201.1. 1 Scope 1
201.1. 2 Object 2
201.1. 3 Collateral standards 2
201.1. 4 Particular standards 2

201.2 Normative references 3

201.3 Terminology and definitions 3

201.4 General requirements 6
201.4. 2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 6
201.4. 2.101 Additional requirements for RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 7
201.4. 3 ESSENTIAL PERFORMANCE 7
201.4. 3.101 * Additional requirements for ESSENTIAL PERFORMANCE 7
201.4. 101 Environmental conditions of use 7

201.5 General requirements for testing of ME EQUIPMENT 7

201.6 Classification of ME EQUIPMENT and ME SYSTEMS 7

201.7 ME EQUIPMENT identification, marking and documents 7
201.7. 2.1 Minimum requirements for marking on ME EQUIPMENT and interchangeable parts 8
201.7. 2.1.101 Additional requirements for minimum requirements for marking on ME EQUIPMENT and interchangeable parts, marking of the packaging 8
201.7. 2.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 8
201.7. 2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts 8
201.7. 4.3 Unit of measure 8
201.7. 4.3.101 Additional requirements for unit of measure 8
201.7. 9 ACCOMPANYING DOCUMENT 9
201.7. 9.1 Additional general requirements 9
201.7. 9.2 Additional requirements for instructions for use 9
201.7. 9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material 9
201.7. 9.2.101 Instructions for use 9
201.7. 9.101 Additional requirements for ACCOMPANYING DOCUMENT 10

201.8 Protection against electrical HAZARDS from ME EQUIPMENT 10

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 10

201.10 Protection against unwanted and excessive radiation HAZARDS 10

201.11 Protection against excessive temperatures and other HAZARDS 10

201.12 Accuracy of controls and instruments and protection against hazardous outputs 10
201.12. 1 Accuracy of controls and instruments 10
201.12. 1.101 Additional requirements for accuracy of controls and instruments 10
201.12. 2 USABILITY 11
201.12. 2.101 * Additional requirements for USABILITY 11

201.13 HAZARDOUS SITUATIONS and fault conditions 11

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 11

201.15 **Construction of ME EQUIPMENT** **11**

201.16 **ME SYSTEMS** **11**

201.17 *** Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS** **11**

201.101 **Laboratory performance requirements** **11**
201.101. 1 *** General test requirements** **11**
201.101. 2 *** Laboratory accuracy** **12**
201.101. 3 *** Time response for a continuous** clinical thermometer **13**

201.102 *** Clinical accuracy validation** **13**
201.102. 1 **Method** **13**
201.102. 2 *** Human subject population requirements** **14**
201.102. 3 *** Clinical bias calculation** **15**
201.102. 4 *** Limits of agreement calculation** **15**
201.102. 5 *** Clinical repeatability calculation** **16**

201.103 *** Probes, probe cable extenders and probe covers** **16**
201.103. 1 **General** **16**
201.103. 2 **Labeling** **17**

202 **Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests** **17**

202.6.2.1.10 **Compliance criteria** **17**

Annexes

Annex C (informative) **Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS** **19**

Annex D (informative) **Symbols on Marking** **22**

Annex AA (informative) **Particular Guidance and rationale** **24**

Annex BB (informative) **REFERENCE TEMPERATURE SOURCE** **37**

Annex CC (informative) **Environmental aspects** **39**

Annex DD (informative) **Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142** **40**

Bibliography **42**

Alphabetized index of defined terms used in this particular standard **45**

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 80601-2-56 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* in cooperation with Subcommittee 62D, *Electrical equipment*, of Technical Committee IEC/TC 62: *Electrical equipment in medical practice*.

ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

— *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

— *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

— *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

— *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

— *Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*

IEC 80601-2-30: *Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*, IEC 80601-2-35: *Particular requirements for basic safety and essential performance of blankets, pads and mattresses intended for heating in medical use*, IEC 80601-2-58: *Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*, IEC 80601-2-59: *Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening* and IEC 80601-2-60: *Particular requirements for basic safety and essential performance of dental equipment* are published by IEC.

Introduction

In this International Standard, the following print types are used.

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this International Standard, the term

— "clause" means one of the 20 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this International Standard are by number only.

In this International Standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This international standard deals with electrical CLINICAL THERMOMETERS, either already available or that will come available in the future.

The purpose of a CLINICAL THERMOMETER is to assess the true temperature of a REFERENCE BODY SITE. The temperature of the PATIENT'S body is an important vital sign in assessing overall health, typically in combination with blood pressure and pulse rate. Determining whether a PATIENT is afebrile or febrile is an important purpose of a CLINICAL THERMOMETER, since being febrile suggests that the PATIENT is ill.

There are different temperatures at each REFERENCE BODY SITE according to the balance between the production, transfer, and loss of heat.[38] CLINICAL ACCURACY of a CLINICAL THERMOMETER is VERIFIED by comparing its OUTPUT TEMPERATURE with that of a REFERENCE THERMOMETER, which has a specified uncertainty for measuring true temperature. For an equilibrium CLINICAL THERMOMETER, the CLINICAL ACCURACY can be sufficiently determined under laboratory conditions that create an equilibrium state between the two thermometers.

For a CLINICAL THERMOMETER that operates in the ADJUSTED MODE, laboratory VERIFICATION alone is not sufficient because the adjustment algorithm for deriving the OUTPUT TEMPERATURE includes the characteristics of the PATIENT and the environment.[3] Therefore the CLINICAL ACCURACY of a CLINICAL THERMOMETER that operates in the ADJUSTED MODE has to be VALIDATED clinically, using statistical methods of comparing its OUTPUT TEMPERATURE with that of a REFERENCE CLINICAL THERMOMETER which has a specified CLINICAL ACCURACY in representing a particular REFERENCE BODY SITE temperature.

For a CLINICAL THERMOMETER that operates in the ADJUSTED MODE**,** the LABORATORY ACCURACY is VERIFIED in a DIRECT MODE and the CLINICAL ACCURACY is VALIDATED in the ADJUSTED MODE (OPERATING MODE) with a sufficiently large group of human subjects.

The intention of this International Standard is to specify the requirements and the test procedures for the VERIFICATION of the LABORATORY ACCURACY for all types of electrical CLINICAL THERMOMETERS as well as for the VALIDATION of the CLINICAL ACCURACY of a CLINICAL THERMOMETER that operates in the ADJUSTED MODE.

INTERNATIONAL STANDARD **ISO 80601-2-56:2009(E)**

Medical electrical equipment —

Part 2-56:
Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

201.1 * Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT. This standard specifies the general and technical requirements for electrical CLINICAL THERMOMETERS. This standard applies to all electrical CLINICAL THERMOMETERS that are used for measuring the body temperature of PATIENTS.

CLINICAL THERMOMETERS can be equipped with interfaces to accommodate secondary indicators, printing equipment, and other auxiliary equipment to create ME SYSTEMS. This standard does not apply to auxiliary equipment.

ME EQUIPMENT that measures a temperature not as a primary purpose, but as a secondary function, is outside the scope of this standard.

EXAMPLE 1 Swan-Ganz thermodilution determination of cardiac output is not in the scope of this standard.

EXAMPLE 2 A Foley catheter that includes a temperature PROBE is in the scope of this standard.

EXAMPLE 3 PATIENT heating ME EQUIPMENT that includes a skin temperature measurement such as infant incubators, heating blankets, heating pads and heating mattresses are not in the scope of this standard, unless they indicate a temperature of a REFERENCE BODY SITE in which they are in the scope of this standard.

Requirements for ME EQUIPMENT intended to be used for non-invasive human febrile temperature screening of groups of individuals under indoor environmental conditions are given in IEC 80601-2-59:2008 and such ME EQUIPMENT is not covered by this standard.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005, 4.2.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a CLINICAL THERMOMETER, as defined in 201.3.206, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the CLINICAL THERMOMETER and the ACCESSORIES needs to be safe. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005, Clause 2, as well as Clause 2 of this particular standard.

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the IEC 60601-1 or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the IEC 60601-1 or applicable collateral standard.

“Amendment” means that the clause or subclause of the IEC 60601-1 or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 6060-1-3, etc.

The term “this standard” is used to make reference to the IEC 60601-1, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the IEC 60601-1 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the IEC 60601-1 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 43.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2006, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
Amendment 1:2008

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

201.3 Terminology and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-6:2006, IEC 60601-1-8:2006, and the following definitions apply.

NOTE An alphabetized index of defined terms is found beginning on page 45.

Additions:

201.3.201
***** ADJUSTED MODE
OPERATING MODE where the OUTPUT TEMPERATURE is calculated by adjusting the signal from the input SENSOR

EXAMPLE Adjustments can include one or more of the following: variations in the SENSOR'S rate of response, ambient temperature, measured temperature, and the thermal, physiological, or anatomical properties of both the MEASURING SITE and the REFERENCE BODY SITE.

NOTE For the purposes of this particular standard, emissivity is considered a thermal or physiological property of the MEASURING SITE, i.e. any CLINICAL THERMOMETER utilizing radiance that is dependant on emissivity is considered to operate in an ADJUSTED MODE.

201.3.202
BLACKBODY
REFERENCE TEMPERATURE SOURCE of infrared radiation made in the shape of a cavity and characterized by precisely known temperature of the cavity walls and having an effective emissivity at the cavity opening as close as practical to unity

201.3.203
CLINICAL ACCURACY
closeness of agreement between the OUTPUT TEMPERATURE of a CLINICAL THERMOMETER and the true value of the temperature of the REFERENCE BODY SITE that the CLINICAL THERMOMETER purports to represent

201.3.204
CLINICAL BIAS
Δ_{cb}
mean difference between OUTPUT TEMPERATURES of a CLINICAL THERMOMETER and a REFERENCE CLINICAL THERMOMETER for the intended REFERENCE BODY SITE with specified LIMITS OF AGREEMENT when measured from selected group of subjects

NOTE LIMITS OF AGREEMENT can also be described as clinical uncertainty.

201.3.205
CLINICAL REPEATABILITY
σ_r
pooled standard deviation (over a selected group of subjects) of changes in multiple OUTPUT TEMPERATURES taken from the same subject from the same MEASURING SITE with the same CLINICAL THERMOMETER by the same OPERATOR within a relatively short time

201.3.206
* CLINICAL THERMOMETER
ME EQUIPMENT used for measuring at the MEASURING SITE and indicating the temperature at the REFERENCE BODY SITE

NOTE The MEASURING SITE can be the same as REFERENCE BODY SITE.

201.3.207
* DIRECT MODE
OPERATING MODE of a CLINICAL THERMOMETER where the OUTPUT TEMPERATURE is an unadjusted temperature that represents the temperature of the MEASURING SITE to which the PROBE is coupled

201.3.208
EXTENDED OUTPUT RANGE
OUTPUT TEMPERATURE range having one or both limits that are outside of the RATED OUTPUT RANGE

201.3.209
FLUID BATH
REFERENCE TEMPERATURE SOURCE containing fluid at a uniform temperature

EXAMPLES Water, oil and air.

201.3.210
LABORATORY ACCURACY
closeness of agreement between the OUTPUT TEMPERATURE of a thermometer and the true value of the measurand

NOTE LABORATORY ACCURACY is sometimes referred to as maximum permissible error.

201.3.211
LIMITS OF AGREEMENT
L_A
the magnitude of a potential disagreement between outputs of two CLINICAL THERMOMETERS equal to double the standard deviation of OUTPUT TEMPERATURE differences when used on the same human subjects

NOTE LIMITS OF AGREEMENT can also be described as clinical uncertainty.

201.3.212
MEASURING SITE
part of a PATIENT where the temperature is measured

EXAMPLES Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin.

201.3.213
OPERATING MODE
state of a CLINICAL THERMOMETER that gives an OUTPUT TEMPERATURE of an intended REFERENCE BODY SITE

201.3.214
OUTPUT RANGE
span between the lowest and highest temperature limits where a CLINICAL THERMOMETER indicates OUTPUT TEMPERATURE within the specified characteristics of LABORATORY ACCURACY

201.3.215
OUTPUT TEMPERATURE
temperature indicated by a thermometer

NOTE Methods of indication can include printed, spoken, displayed and remotely displayed.

201.3.216
PROBE
part of a CLINICAL THERMOMETER that provides a thermal coupling between the SENSOR and the PATIENT

NOTE Thermal coupling can be contact or non-contact.

201.3.217
PROBE CABLE EXTENDER
cable that connects a CLINICAL THERMOMETER to a PROBE

NOTE 1 Not every CLINICAL THERMOMETER utilizes a PROBE CABLE EXTENDER.

NOTE 2 A PROBE CABLE EXTENDER can be an APPLIED PART.

201.3.218
PROBE COVER
disposable or reusable ACCESSORY of a CLINICAL THERMOMETER that provides a sanitary barrier between the PROBE and the PATIENT

201.3.219
* REFERENCE BODY SITE
part of a PATIENT to which the OUTPUT TEMPERATURE refers

EXAMPLES Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin

201.3.220
REFERENCE CLINICAL THERMOMETER
RCT
CLINICAL THERMOMETER having established CLINICAL ACCURACY and LABORATORY ACCURACY, which is used for CLINICAL ACCURACY VALIDATION of another CLINICAL THERMOMETER

201.3.221
REFERENCE TEMPERATURE SOURCE
source of a thermal energy whose temperature is measured by a REFERENCE THERMOMETER

EXAMPLES BLACKBODY, FLUID BATH.

201.3.222
REFERENCE THERMOMETER
equilibrium thermometer of a contact type for laboratory application whose calibration is traceable to a national standard of temperature, with a specified accuracy and associated uncertainty

NOTE An equilibrium thermometer can also be described as a zero-heat flow thermometer.

EXAMPLE Platinum resistance thermometer with calibration traceable to a national standard of temperature.

201.3.223
REPROCESSING
any activity, not specified in the ACCOMPANYING DOCUMENT, that renders a used product ready for re-use

NOTE 1 The term "REPROCESSED" is used to designate the corresponding status.

NOTE 2 Such activities are often referred to as refinishing, restoring, recycling, refurbishing, repairing or remanufacturing.

NOTE 3 Such activities can occur in healthcare facilities.

201.3.224
SENSOR
part of the CLINICAL THERMOMETER that converts thermal energy into an electrical signal

201.3.225
TEST MODE
state of a CLINICAL THERMOMETER where the OUTPUT TEMPERATURE represents the temperature measured by the SENSOR and is not adjusted for a REFERENCE BODY SITE or the rate of response of the SENSOR

NOTE 1 The TEST MODE can be used for the determination of the LABORATORY ACCURACY of the CLINICAL THERMOMETER.

NOTE 2 The TEST MODE can be the DIRECT MODE of the CLINICAL THERMOMETER.

201.4 General requirements

IEC 60601-1:2005, Clause 4 applies, except as follows:

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Additional subclause:

201.4.2.101 Additional requirements for RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

When performing the RISK MANAGEMENT PROCESS required by IEC 60601-1:2005, 4.2, the analysis shall consider the RISKS of changing environmental conditions for the CLINICAL THERMOMETER and provide guidance regarding the RESIDUAL RISKS in the instruction for use.

NOTE PORTABLE CLINICAL THERMOMETERS can undergo changing environmental conditions that can affect the LABORATORY ACCURACY.

Compliance is checked by inspection of the instructions for use and the RISK MANAGEMENT FILE.

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of the CLINICAL THERMOMETER or at least one of the following:	201.101.2
— generation of a TECHNICAL ALARM CONDITION;	201.12.1.101
— not providing an OUTPUT TEMPERATURE;	
— marking the ambient temperature operating range.	201.4.101

Additional subclause:

201.4.101 Environmental conditions of use

A CLINICAL THERMOMETER intended for home healthcare use shall operate in NORMAL USE over the ranges of

— an ambient temperature operating range from 15 °C to 35 °C; and

— a relative humidity range of 15 % to 85 % (non-condensing);

or the CLINICAL THERMOMETER shall be marked with the limited environmental operation range and the instructions for use shall disclose the warning of the consequences of operation outside of that range.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005, Clause 5 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, Clause 7 applies, except as follows:

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and interchangeable parts

Additional subclause:

201.7.2.1.101 Additional requirements for minimum requirements for marking on ME EQUIPMENT and interchangeable parts, marking of the packaging

The packaging of a CLINICAL THERMOMETER and PROBE shall be marked with the following information:

a) MEASURING SITE and REFERENCE BODY SITE;

b) details to enable the OPERATOR to identify the mode of operation of the CLINICAL THERMOMETER and the contents of the packaging;

EXAMPLE This package contains a predictive thermometer that estimates the PATIENT's temperature and 10 protective barriers.

c) if sterile, the appropriate symbols from ISO 15223-1:2007 (see Table D.2.101, Symbols 3 to 8);

d) for a CLINICAL THERMOMETER or PROBE with an expiration date, ISO 15223-1:2007, Symbol 5.12 (see Table D.2.101, Symbol 2);

e) for a single use CLINICAL THERMOMETER or PROBE, the words “single use only” or “do not reuse”, in a language that is acceptable to the intended OPERATOR, or ISO 15223-1:2007, Symbol 5.2 (see Table D.2.101, Symbol 1);

f) any special storage and/or handling instructions.

For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent.

Compliance is checked by inspection.

201.7.2.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

A CLINICAL THERMOMETER shall have CLEARLY LEGIBLE markings with the following information:

a) the symbol “°C” or “°F” adjacent to the OUTPUT TEMPERATURE, if not indicated at the display. If switching between degrees Fahrenheit and degrees Celsius is possible, the respective unit of measure of the OUTPUT TEMPERATURE shall be indicated unambiguously;

b) intended MEASURING SITE;

c) that a new PROBE COVER shall be used prior to next measurement, if necessary to maintain ESSENTIAL PERFORMANCE.

Compliance is checked by inspection.

201.7.4.3 Unit of measure

Additional subclause:

201.7.4.3.101 Additional requirements for unit of measure

A CLINICAL THERMOMETER shall express the temperature in either degrees Celsius, °C or degrees Fahrenheit, °F, or both.

The CLINICAL THERMOMETER shall clearly indicate the unit of measure.

Compliance is checked by inspection and functional testing.

201.7.9 ACCOMPANYING DOCUMENT

201.7.9.1 Additional general requirements

Amendment (replace the first dash with):

— Name or trade name and address of the MANUFACTURER or an authorized representative within the locale, to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Additional requirements for instructions for use

Additional subclause:

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The instructions for use shall include all necessary information, as regards toxicity and/or action on tissues, about materials with which the PATIENT or any other person can come into contact and information on RESIDUAL RISKS for children, pregnant or nursing women and, if applicable, any appropriate precautionary measures;

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by inspection.

201.7.9.2.101 Instructions for use

The instructions for use shall include:

a) the MEASURING SITE and REFERENCE BODY SITE of the CLINICAL THERMOMETER;

b) if applicable, the recommended minimum measuring time and minimum time between measurements for each intended MEASURING SITE;

c) the RATED OUTPUT RANGE for each intended REFERENCE BODY SITE;

d) the LABORATORY ACCURACY in the RATED OUTPUT RANGE and, if equipped, the LABORATORY ACCURACY in the RATED EXTENDED OUTPUT RANGE;

e) for CLINICAL THERMOMETERS intended to be used with a PROBE COVER:

   1) instructions for the application of a PROBE COVER;

   2) information about the behaviour of the CLINICAL THERMOMETER when used without the PROBE COVER;

f) whether the CLINICAL THERMOMETER is a DIRECT MODE or an ADJUSTED MODE CLINICAL THERMOMETER;

g) instructions for selection and replacement of the INTERNAL ELECTRICAL POWER SOURCE, if applicable;

   EXAMPLE Battery replacement.

h) details of the nature and frequency of any maintenance and/or calibration needed to ensure that the CLINICAL THERMOMETER operates properly and safely;

i) information concerning the disposal of the CLINICAL THERMOMETER and its components;

   EXAMPLES Battery or PROBE COVER disposal.

j) if the CLINICAL THERMOMETER or its parts are intended for single use, information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the CLINICAL THERMOMETER or its parts would be re-used;

k) date of issue or the revision of the instructions for use;

l) an explanation of the meaning of the IP classification marked on the CLINICAL THERMOMETER.

Compliance is checked by inspection.

Additional subclause:

201.7.9.101 Additional requirements for ACCOMPANYING DOCUMENT

Unless the CLINICAL THERMOMETER is equipped with a TEST MODE or DIRECT MODE, the ACCOMPANYING DOCUMENT shall include the correction method to derive unadjusted temperatures from OUTPUT TEMPERATURE measured in the ADJUSTED MODE.

Compliance is checked by inspection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005, Clause 8 applies.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005, Clause 11 applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclause:

201.12.1.101 Additional requirements for accuracy of controls and instruments

When the CLINICAL THERMOMETER is not capable of indicating a temperature within the LABORATORY ACCURACY, it shall provide a TECHNICAL ALARM CONDITION or it shall not provide an OUTPUT TEMPERATURE. Alternatively a CLINICAL THERMOMETER may be marked with the ambient temperature operating range.

NOTE 1 Possible causes include:

a) low voltage of the INTERNAL ELECTRICAL POWER SOURCE;
b) OUTPUT TEMPERATURE outside the RATED OUTPUT RANGE or RATED EXTENDED OUTPUT RANGE;
c) CLINICAL THERMOMETER temperature outside the ambient temperature operating range.

The OUTPUT TEMPERATURE of CLINICAL THERMOMETERS should cover the minimum RATED OUTPUT RANGE from 35,0 °C to 42,0 °C.

NOTE 2 In some applications a wider RATED OUTPUT RANGE can be needed.

NOTE 3 In some applications a narrower RATED OUTPUT RANGE can be needed (e.g. ovulation CLINICAL THERMOMETER).

Compliance is checked by inspection and functional testing.

201.12.2 USABILITY

Additional subclause:

201.12.2.101 * Additional requirements for USABILITY

In addition to the requirements of IEC 60601-1:2005, 12.2, for CLINICAL THERMOMETERS intended for home healthcare use, the display of OUTPUT TEMPERATURE shall be at least 4 mm high or optically magnified so as to appear that height.

For CLINICAL THERMOMETERS with a segmented indication display, a functional test of all segments shall be performed after activation.

Compliance is checked by inspection and inspection of the USABILITY ENGINEERING FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005, Clause 13 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005, Clause 15 applies.

201.16 ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 17 applies.

Additional subclauses:

201.101 Laboratory performance requirements

201.101.1 * General test requirements

Laboratory performance shall be assessed in DIRECT MODE or in TEST MODE under the same conditions. If a TEST MODE or DIRECT MODE is not available, use the correction method to derive unadjusted temperatures from OUTPUT TEMPERATURE in accordance with the ACCOMPANYING DOCUMENT.

A CLINICAL THERMOMETER intended for use with a PROBE COVER, shall be tested together with the PROBE COVER as indicated in the instructions for use. A new PROBE COVER shall be used for each OUTPUT TEMPERATURE measurement.

NOTE A CLINICAL THERMOMETER OPERATING MODE whose accuracy cannot be VERIFIED by utilizing a FLUID BATH is also required to be evaluated according to 201.102.

Compliance is checked by inspection and inspection of the ACCOMPANYING DOCUMENT.

201.101.2 * Laboratory accuracy

The LABORATORY ACCURACY within the RATED OUTPUT RANGE in NORMAL USE shall

— not be greater than 0,3 °C for a continuous CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER, and

— not be greater than 0,2 °C otherwise.

The LABORATORY ACCURACY, within the RATED EXTENDED OUTPUT RANGE in NORMAL USE, shall not be greater than 0,4 °C unless CLINICAL THERMOMETER indicates that the measured temperature is outside of the RATED OUTPUT RANGE.

If the PROBE is separable from the CLINICAL THERMOMETER, they may be tested separately.

NOTE For some applications, improved LABORATORY ACCURACY can be needed (e.g. ovulation CLINICAL THERMOMETER).

Compliance is checked with the following test.

*a) * Utilize a REFERENCE TEMPERATURE SOURCE, which is either a FLUID BATH or a BLACKBODY radiator as described in Annex BB. Ensure that the temperature supplied by the REFERENCE TEMPERATURE SOURCE has a total uncertainty (covering factor k = 2) of not greater than 0,07 °C.*

b) Place the CLINICAL THERMOMETER into a climatic chamber and set the ambient temperature and humidity to approximately the mid range of temperature and humidity as indicated in the ACCOMPANYING DOCUMENT.

c) Set the temperature of the REFERENCE TEMPERATURE SOURCE to approximately the midpoint of the RATED OUTPUT RANGE. Stabilize the CLINICAL THERMOMETER at given conditions of ambient temperature and humidity for a minimum of 30 min, or longer if indicated in the ACCOMPANYING DOCUMENT.

d) Measure the temperature of the REFERENCE TEMPERATURE SOURCE with both the CLINICAL THERMOMETER and a REFERENCE THERMOMETER. Record the results.

e) Repeat c) and d), twice, once setting the temperature of the REFERENCE TEMPERATURE SOURCE to within 1 °C of the upper limit and once within 1 °C of the lower limit of the RATED OUTPUT RANGE.

f) If the CLINICAL THERMOMETER is provided with an EXTENDED OUTPUT RANGE, repeat e) twice, once setting the temperature of the REFERENCE TEMPERATURE SOURCE to within 0,5 °C of the upper limit and once within 0,5 °C of the lower limit of the RATED EXTENDED OUTPUT RANGE.

g) Repeat c) through f) at four points, the combinations of upper and lower limits of environmental temperature and humidity ranges as indicated in the ACCOMPANYING DOCUMENT.

h) Calculate the measurement error, e, for each individual OUTPUT TEMPERATURE measurement using Equation (1).

i) Ensure that the measurement error meets the requirement.

The error of an individual OUTPUT TEMPERATURE measurement is indicated by Equation (1).

$$e = t_{TUT} - t_{ref} \quad (1)$$

where

t_{TUT} *is the individual OUTPUT TEMPERATURE of the CLINICAL THERMOMETER under test (TUT) when measuring the REFERENCE TEMPERATURE SOURCE, and*

t_{ref} *is the corresponding OUTPUT TEMPERATURE of the REFERENCE TEMPERATURE SOURCE measured by the REFERENCE THERMOMETER.*

201.101.3 * Time response for a continuous CLINICAL THERMOMETER

The transient response for a continuous CLINICAL THERMOMETER shall be characterized and disclosed in the instruction for use.

Compliance is checked by inspection of the instructions for use and with the following test.

a) Utilize two REFERENCE TEMPERATURE SOURCES, which are FLUID BATHS, BLACKBODIES or specially designed thermal sources as described in Annex BB.

b) Set the temperature of the first REFERENCE TEMPERATURE SOURCE to approximately the middle of the RATED OUTPUT RANGE. Set the temperature of the second REFERENCE TEMPERATURE SOURCE to approximately 2 °C higher than the first REFERENCE TEMPERATURE SOURCE. Ensure that the temperature of the second REFERENCE TEMPERATURE SOURCE is within the RATED OUTPUT RANGE of the CLINICAL THERMOMETER.

c) For 5 minutes, or longer if necessary to achieve thermal equilibrium, thermally couple the PROBE of the CLINICAL THERMOMETER to the first REFERENCE TEMPERATURE SOURCE. Note the time and immediately move the PROBE to the second REFERENCE TEMPERATURE SOURCE.

d) Continuously monitor the OUTPUT TEMPERATURE until the new temperature reading remains within the LABORATORY ACCURACY limits of the second REFERENCE TEMPERATURE SOURCE and is within the LABORATORY ACCURACY of the CLINICAL THERMOMETER. Note the time.

e) Note the difference between the two times and record the heating transient time.

f) Set the temperature of the second REFERENCE TEMPERATURE SOURCE to approximately 2 °C lower than the first REFERENCE TEMPERATURE SOURCE. Ensure that the temperature of the second REFERENCE TEMPERATURE SOURCE is within the RATED OUTPUT RANGE of the CLINICAL THERMOMETER.

g) Repeat c) through d).

h) Note the difference between the two times and record the cooling transient time.

i) Ensure that the transient time for both heating and cooling is less than the recommended minimum measuring time indicated in the ACCOMPANYING DOCUMENT.

201.102 * CLINICAL ACCURACY VALIDATION

201.102.1 Method

ADJUSTED MODE CLINICAL THERMOMETERS shall be VALIDATED for CLINICAL ACCURACY in each ADJUSTED MODE. The results of CLINICAL ACCURACY VALIDATION shall be disclosed in the ACCOMPANYING DOCUMENT. This disclosure shall include: the CLINICAL BIAS, Δ_{cb}, with its LIMITS OF AGREEMENT, L_A, the CLINICAL REPEATABILITY, σ_r, the REFERENCE BODY SITE and MEASURING SITE for each OPERATING MODE.

NOTE 1 CLINICAL BIAS is the mean difference between OUTPUT TEMPERATURES of the CLINICAL THERMOMETER under test (TUT) and the RCT for a specific REFERENCE BODY SITE when measured from a selected group of subjects. The CLINICAL BIAS for each OPERATING MODE of the TUT defines closeness between the TUT OUTPUT TEMPERATURE and that of the RCT.

NOTE 2 Any CLINICAL THERMOMETER OPERATING MODE whose accuracy cannot be VERIFIED by utilizing a FLUID BATH is considered an ADJUSTED MODE CLINICAL THERMOMETER.

NOTE 3 The CLINICAL THERMOMETER can have more than one OPERATING MODE with different CLINICAL ACCURACIES.

The CLINICAL ACCURACY VALIDATION shall be conducted in accordance with ISO 14155-1:2003 and ISO 14155-2:2003.

NOTE 4 This particular standard specifies that during a CLINICAL ACCURACY VALIDATION of a CLINICAL THERMOMETER, characteristics that represent CLINICAL ACCURACY (i.e. the CLINICAL BIAS with its LIMITS OF AGREEMENT and CLINICAL REPEATABILITY) are evaluated. These characteristics are evaluated from the same data set obtained with a CLINICAL THERMOMETER under test (TUT) and a REFERENCE CLINICAL THERMOMETER (RCT), both indicating the OUTPUT TEMPERATURE of the same REFERENCE BODY SITE.

A CLINICAL THERMOMETER intended for use with a PROBE COVER, shall be tested together with the PROBE COVER as indicated in the instructions for use. A new PROBE COVER shall be used for each OUTPUT TEMPERATURE measurement.

Consider compliance with the requirements of this subclause to exist when the requirements of 201.102.2, 201.102.3, 201.102.4 and 201.102.5 have been fulfilled, by inspection of the instructions for use and with the following test.

a) *Temperatures measured with the TUT shall be obtained in the OPERATING MODE being evaluated and with the PATIENT population indicated in the instructions for use according to 201.102.2. Before and after the tests, LABORATORY ACCURACY of the RCT shall be VERIFIED with a REFERENCE TEMPERATURE SOURCE.*

b) *Take OUTPUT TEMPERATURES from the TUT and the RCT concurrently, or sequentially when using the same MEASURING SITE, using the measuring time as indicated in the instructions for use. Use the RCT according to its instructions for use.*

c) *Perform at least three consecutive measurement procedures, as indicated in the instructions for use, with the TUT and at least one temperature with an RCT for each subject. Wait between individual measurements as indicated in the instructions for use. See also 201.101.1. For febrile subjects less than five years of age, only one measurement may be taken.*

   NOTE Care should be taken to ensure that the actual temperatures of the MEASURING SITES of the TUT and RCT remain stable during a series of measurements.

d) *Repeat b) and c) for each subject in the study. Take care to exclude subjects with medical conditions which might skew CLINICAL ACCURACY VALIDATION results such as inflammation at the MEASURING SITE and subjects using medications known to affect body or REFERENCE BODY SITE temperature.*

   EXAMPLES Antipyretics, barbiturates, thyroid preparations, antipsychotics, recent immunizations.

201.102.2 * Human subject population requirements

The total number of febrile subjects shall be not less than 30 % and not greater than 50 % of all subjects in the selected age group.

NOTE 1 The first temperature out of three measurements is used in calculation of CLINICAL BIAS and LIMITS OF AGREEMENT. All three OUTPUT TEMPERATURE measurements are used in calculation of the CLINICAL REPEATABILITY.

NOTE 2 For the purpose of CLINICAL ACCURACY VALIDATION, a febrile subject is defined as a subject having
- an elevated core or rectal temperature of 38,0 °C (100,4 °F) or higher as measured by an RCT;
- an elevated sublingual temperature of 37,5 °C (99,5 °F) or higher as measured by an RCT; or
- an elevated axillary temperature of 37,2 °C (99,0 °F) or higher as measured by an RCT.

CLINICAL ACCURACY VALIDATION shall be carried out on all age groups indicated in the instructions for use. The number of subjects in each age group shall be sufficiently large to minimize the effect of random components of measurement error. The minimum number of subjects in an age group shall be at least 35, at least 15 in subgroup A1 or A2 if subgroup A is not explicitly excluded in the documentation and the minimum number of subjects in all age groups shall be not less than 105. The age groups shall be developed with the guidelines of Table 201.102. Subjects may be PATIENTS.

Table 201.102 — Subject age groups

Age group	Age [5]
A1	0 up to 3 months
A2	3 months up to one year
B	older than one and younger than five years
C	older than five years

201.102.3 * CLINICAL BIAS calculation

To evaluate the CLINICAL BIAS for the OPERATING MODE being evaluated, use the first CLINICAL THERMOMETER under test (TUT) OUTPUT TEMPERATURE out of three and the corresponding RCT OUTPUT TEMPERATURE from each subject in a test group. The CLINICAL BIAS for the specified REFERENCE BODY SITE and age group is calculated from Equation (2).

$$\Delta_{\mathbf{cb}} = \frac{\sum_{i=1}^{n}\left(t_{\mathrm{TUT},i} - t_{\mathrm{RCT},i}\right)}{n} \tag{2}$$

where

i is the index number for an individual subject;

n is the total number of subjects per MEASURING SITE and age group;

t_{TUT}, t_{RCT} are the observed OUTPUT TEMPERATURES from the TUT and the RCT.

201.102.4 * LIMITS OF AGREEMENT calculation

To calculate the LIMITS OF AGREEMENT, L_{A}, use Equation (3).

$$L_{\mathrm{A}} = 2 \times \sigma_{\Delta\mathrm{cb}} \tag{3}$$

where

$\sigma_{\Delta\mathrm{cb}}$ is calculated using Equation (4).

To calculate the standard deviation, $\sigma_{\Delta\mathrm{cb}}$, use the first measurement of the CLINICAL THERMOMETER under test (TUT) OUTPUT TEMPERATURE out of three measurements and the corresponding RCT OUTPUT TEMPERATURE of each subject for the OPERATING MODE being evaluated using Equation (4).

$$\sigma_{\Delta\mathrm{cb}} = \sqrt{\frac{\sum_{i=1}^{n}\left[\left(t_{TUT,i} - t_{RCT,i}\right) - \Delta\mathrm{cb}\right]^2}{n-1}} \tag{4}$$

where

i is the index number for an individual subject;

n is the total number of subjects per MEASURING SITE and age group;

t_{TUT}, t_{RCT} are temperatures indicated by the TUT and the RCT respectively;

Δ_{cb} is the CLINICAL BIAS as calculated in Equation (2).

201.102.5 * CLINICAL REPEATABILITY calculation

An ADJUSTED MODE CLINICAL THERMOMETER that makes continuous estimates of the REFERENCE BODY SITE temperature shall be exempt from the requirements of this subclause.

CLINICAL REPEATABILITY, for a particular OPERATING MODE, is determined for the subject population of all age groups given in Table 201.102 combined. Febrile subjects less than five years of age may be excluded.

CLINICAL REPEATABILITY is calculated by a pooled standard deviation of triplicate measurements over the entire population of subjects. First, calculate the standard deviation, σ_j, of the three OUTPUT TEMPERATURE measurements ($t_{1,j}$, $t_{2,j}$, and $t_{3,j}$) for each subject j using Equation (5).

$$\sigma_{j=}\sqrt{\frac{\sum_{i=1}^{m}\left(t_{TUTi}-\overline{t_{TUTj}}\right)^2}{m-1}} \tag{5}$$

where

$\overline{t_{TUT,j}}$ is the average of the OUTPUT TEMPERATURES on subject j; and

m is the number of OUTPUT TEMPERATURE measurements on the subject.

NOTE m is typically equal to 3.

Then calculate a pooled standard deviation (the CLINICAL REPEATABILITY), σ_r, for all subjects using Equation (6).

$$\sigma_r = \sqrt{\frac{\sigma_1^2+\sigma_2^2+\ldots+\sigma_j^2+\ldots.+\sigma_N^2}{N}} \tag{6}$$

where

N is the total number of subjects of all age groups in a study.

201.103 * PROBES, PROBE CABLE EXTENDERS and PROBE COVERS

201.103.1 General

All PROBES, PROBE CABLE EXTENDERS and PROBE COVERS shall comply with the requirements of this particular standard, whether they are produced by the MANUFACTURER of the CLINICAL THERMOMETER or by another entity ("third party manufacturer" or healthcare provider) or are REPROCESSED.

MANUFACTURERS of a PROBE, PROBE CABLE EXTENDER and PROBE COVER, including a REPROCESSED PROBE, PROBE CABLE EXTENDER and PROBE COVER, shall conduct tests to ensure that all CLINICAL THERMOMETER specifications are met with each MODEL OR TYPE REFERENCE of CLINICAL THERMOMETER with which the PROBE, PROBE CABLE EXTENDERS or PROBE COVER is intended to be used. The ACCOMPANYING DOCUMENT of PROBES,

PROBE CABLE EXTENDERS and PROBE COVERS, including those that are REPROCESSED, shall list all CLINICAL THERMOMETERS with which compatibility is claimed.

It is the responsibility of the MANUFACTURER of a PROBE, PROBE CABLE EXTENDER and PROBE COVER, including a REPROCESSED PROBE, PROBE CABLE EXTENDER and PROBE COVER, to have their PROCESSES VALIDATED to ensure that any new or REPROCESSED product complies with the requirements of this particular standard.

Compliance is checked by the tests of this particular standard.

201.103.2 Labeling

The MODEL OR TYPE REFERENCE of at least one CLINICAL THERMOMETER shall be included in the ACCOMPANYING DOCUMENT provided with each PROBE, PROBE CABLE EXTENDER and PROBE COVER, compliant with 201.103.1.

Statements shall be included in the ACCOMPANYING DOCUMENT of each PROBE, PROBE CABLE EXTENDER and PROBE COVER to the effect that

a) they are designed for use with specific thermometer or monitoring equipment,

b) the OPERATOR is responsible for checking the compatibility of the thermometer or monitoring equipment, probe, probe cable extender and probe cover before use, and

c) incompatible components can result in degraded performance.

Additional information is found in 201.103.1.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENT.

202 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.6.2.1.10 Compliance criteria

IEC 60601-1-2:2007, 6.2.1.10, is replaced by:

Under the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2007, 6.2, CLINICAL THERMOMETERS shall provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 1 A CLINICAL THERMOMETER is not considered a LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM.

The following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:

a) no permanent degradation or loss of function which is not recoverable, due to damage of ME EQUIPMENT (components) or software, or loss of data shall be observed at any IMMUNITY TEST LEVEL;

b) no change of OPERATING MODE;

c) LABORATORY ACCURACY at any point in the RATED OUTPUT RANGE and in the RATED EXTENDED OUTPUT RANGE as indicated in 201.101.2 or generation of either a TECHNICAL ALARM CONDITION or an indication of abnormal operation.

For testing according IEC 60601-1-2:2007, 6.2.3, 6.2.6 and 6.2.8, the ME EQUIPMENT shall maintain LABORATORY ACCURACY at any point in the RATED OUTPUT RANGE and in the RATED EXTENDED OUTPUT RANGE as indicated in 201.101.2.

For testing according to IEC 60601-1-2:2007, 6.2.2, 6.2.4, 6.2.5 and 6.2.7, temporary degradation or loss of function or performance which does not require OPERATOR intervention is acceptable.

In the event of disruption during immunity tests, the CLINICAL THERMOMETER shall recover from any disruption within 30 s.

In addition to these requirements, CLINICAL THERMOMETERS intended for use during PATIENT transport outside the healthcare facility shall comply with IEC 60601-1-2:2007, 6.2.3.1 a) at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2,5 GHz (additional information is found in IEC 60601-1-2:2007, Table 9).

Compliance is checked by application of the tests in IEC 60601-1-2:2007, 6.2. Evaluate the response of the CLINICAL THERMOMETER during and after these tests in accordance with the above.

Annexes

IEC 60601-1:2005, Annexes apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS, or their parts

Addition:

201.C.1.101 Marking on the outside of a CLINICAL THERMOMETER or its parts

Additional requirements for marking on the outside of a CLINICAL THERMOMETER or its parts are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a CLINICAL THERMOMETER or its parts

Description of marking	Subclause
Intended MEASURING SITE	201.7.2.101 b)
Limited environmental operation range, if applicable	201.4.101 201.12.1.101
On the packaging, any special storage and/or handing instructions	201.7.2.1.101 f)
On the packaging, appropriate sterility symbol, if applicable	201.7.2.1.101 c)
On the packaging, expiration date, if applicable	201.7.2.1.101 d)
On the packaging, for single use only, if applicable	201.7.2.1.101 e)
On the packaging, MEASURING SITE and REFERENCE BODY SITE	201.7.2.1.101 a)
On the packaging, mode of operation of CLINICAL THERMOMETER and contents of package	201.7.2.1.101 b)
Symbol "°C" or "°F", as appropriate	201.7.2.101 a)
That a new PROBE COVER shall be used prior to the next measurement, if applicable	201.7.2.101 c)

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

201.C.4.101 ACCOMPANYING DOCUMENTS, general, of a CLINICAL THERMOMETER

Additional requirements for ACCOMPANYING DOCUMENTS, general, of a CLINICAL THERMOMETER are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general, of a CLINICAL THERMOMETER

Description of marking	Subclause
Correction method to derive the unadjusted temperature from the OUTPUT TEMPERATURE measured in the ADJUSTED MODE, if applicable	201.7.9.101
Correction method to derive the unadjusted temperature from the OUTPUT TEMPERATURE, if applicable	201.101.1
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, all CLINICAL THERMOMETERS with which compatibility is claimed	201.103.1
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, statements to the effect that: they are designed for use with specific thermometer or monitoring equipment	201.103.2 a)
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, statements to the effect that: the OPERATOR is responsible for checking the compatibility of the thermometer or monitoring equipment, probe, probe cable extender and probe cover before use	201.103.2 b)
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, statements to the effect that: incompatible components can result in degraded performance	201.103.2 c)
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, the MODEL OR TYPE REFERENCE of at least one CLINICAL THERMOMETER	201.103.2
For an ADJUSTED MODE CLINICAL THERMOMETER, the results of the CLINICAL ACCURACY VALIDATION	201.102.1
Name and address of the MANUFACTURER or authorized representative	201.7.9.1

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

201.C.5.101 ACCOMPANYING DOCUMENTS, instructions for use of a CLINICAL THERMOMETER

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of a CLINICAL THERMOMETER are found in Table 201.C.103.

Table 201.C.103 — ACCOMPANYING DOCUMENTS, instructions for use of a CLINICAL THERMOMETER

Description of marking	Subclause
All necessary information, as regards toxicity and/or action on tissues	201.7.9.2.14.101
An explanation of the meaning of the IP classification	201.7.9.2.101 l)
Characteristics and technical factors known to the MANUFACTURER that could pose a RISK if a single use CLINICAL THERMOMETER or its parts would be re-used	201.7.9.2.101 j)
Consequences of operation outside of the limited environmental operation range, if applicable	201.4.101
Date of issue or the revision of the instructions for use	201.7.9.2.101 k)
Details of the nature and frequency of any maintenance and/or calibration needed to ensure that the CLINICAL THERMOMETER operates properly and safely	201.7.9.2.101 h)
For a continuous CLINICAL THERMOMETER, the transient response	201.101.3
Information about the behaviour of the CLINICAL THERMOMETER when used without the PROBE COVER, if applicable	201.7.9.2.101 e) 2)
Information concerning the disposal of the CLINICAL THERMOMETER and its components	201.7.9.2.101 i)
Instructions for application of a PROBE COVER, if applicable	201.7.9.2.101 e) 1)
Instructions for selection and replacement of the INTERNAL ELECTRICAL POWER SOURCE	201.7.9.2.101 g)
LABORATORY ACCURACY in the RATED OUTPUT RANGE	201.7.9.2.101 d)
LABORATORY ACCURACY in the RATED EXTENDED OUTPUT RANGE, if applicable	201.7.9.2.101 d)
MEASURING SITE and REFERENCE BODY SITE	201.7.9.2.101 a)
RATED OUTPUT RANGE for each intended REFERENCE BODY SITE	201.7.9.2.101 c)
Recommended minimum measuring time and minimum time between measurements, if applicable	201.7.9.2.101 b)
RESIDUAL RISKS associated with changing environmental conditions	201.4.2.101
Whether the CLINICAL THERMOMETER is a DIRECT MODE or an ADJUSTED MODE CLINICAL THERMOMETER	201.7.9.2.101 f)

Annex D
(informative)

Symbols on Marking

IEC 60601-1:2005, Annex D applies, except as follows:

Addition:

Table D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title
1		ISO 7000-1051 (Symbol 5:2 ISO 15223-1:2007)	**Do not re-use**
2	 (YYYY-MM)	ISO 7000-2607 (Symbol 5:12 ISO 15223-1:2007)	**Use by date**
3		ISO 7000-2499 (Symbol 5:20 ISO 15223-1:2007)	**Sterile**
4		ISO 7000-2500 (Symbol 5.21 ISO 15223-1:2007)	**Sterilized using aseptic processing techniques**
5		ISO 7000-2501 (Symbol 5.22 ISO 15223:2007)	**Sterilized using ethylene oxide**
6		ISO 7000-2502 (Symbol 5.23 ISO 15223-1:2007)	**Sterilized using irradiation**

Table D.2.101 *(continued)*

No	Symbol	Reference	Title
7		ISO 7000-2503 (Symbol 5:24 ISO 15223-1:2007)	**Sterilized using steam or dry heat**
8		ISO 7000-2608 (Symbol 5:25 ISO 15223-1:2007)	**Do not resterilize**
9		ISO 7000-2606 (Symbol 5:27 ISO 15223-1:2007)	**Do not use if package is damaged**

Annex AA
(informative)

Particular Guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some requirements of ISO 80601-2-56, and is intended for those who are familiar with the subject of ISO 80601-2-56 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 80601-2-56 necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses and subclauses in ISO 80601-2-56. The numbering is, therefore, not consecutive.

AA.201.1 Scope, object and related standards

This particular standard addresses a range of MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) generally known as CLINICAL THERMOMETERS. This ME EQUIPMENT has been widely used to measure PATIENT temperature during monitoring and treatment of disease. Examples of applications include detection of fever, determination of the time of ovulation, monitoring of a physiological response to various medications and procedures, effects of exercise and physical work, and evaluation of mental state.

CLINICAL THERMOMETERS are designed and fabricated as PORTABLE, transit-operable, or HAND-HELD ME EQUIPMENT for home healthcare and clinical use, or as parts of the STATIONARY ME EQUIPMENT. The requirements and test procedures of this standard have been developed with the intent to make them applicable to a broad range of present and future CLINICAL THERMOMETER technologies, while assuring that every CLINICAL THERMOMETER that conforms to this standard provides an acceptable degree of diagnostic value and acceptable RISK. There are several RISKS associated with use of this type of ME EQUIPMENT. An obvious RISK is a misdiagnosis - for example, a false negative or false positive detection of a fever which leads to a wrong treatment of a PATIENT. Another RISK is a possible injury of a PATIENT or OPERATOR by the CLINICAL THERMOMETER or its components. RISK CONTROL is the main purpose of this standard which describes the requirements and procedures that assure acceptable levels of CLINICAL ACCURACY and functionality, which should be maintained over the EXPECTED SERVICE LIFE of the CLINICAL THERMOMETER.

AA.201.3.201 ADJUSTED MODE

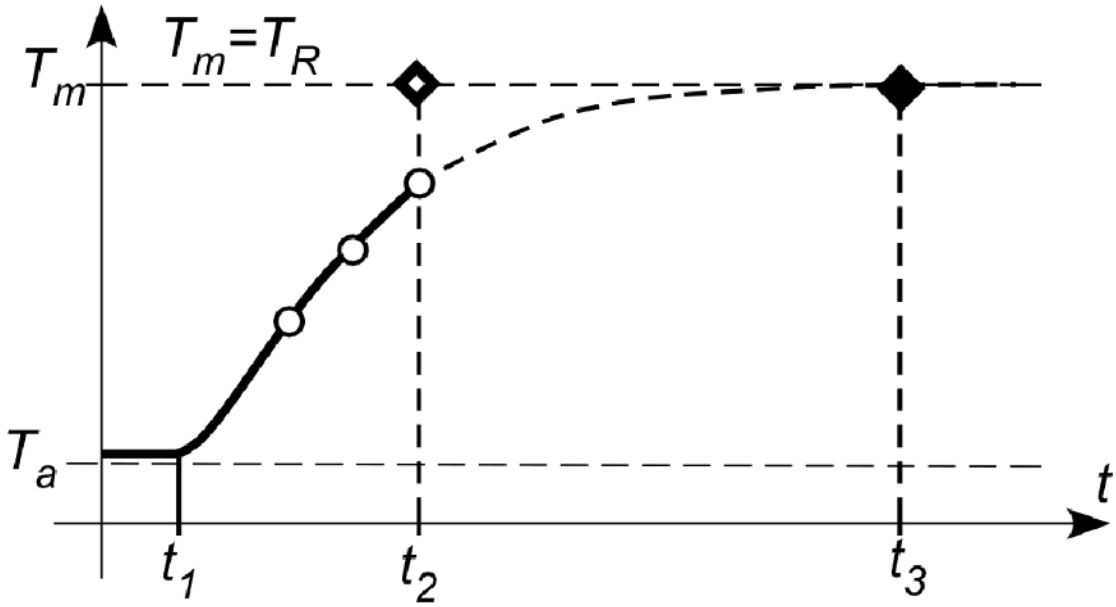
The OUTPUT TEMPERATURE indicated by a CLINICAL THERMOMETER is not necessarily the same as the temperature of the SENSOR that is thermally coupled to the MEASURING SITE. In the DIRECT MODE the OUTPUT TEMPERATURE indicated by a CLINICAL THERMOMETER is the same as the temperature of the SENSOR that is thermally coupled to the MEASURING SITE. Often, DIRECT MODES are inconvenient. For example, the time response for an accurate measurement might be too slow or it might be impossible to place the SENSOR close to the desired body site.

For some CLINICAL THERMOMETERS, the OUTPUT TEMPERATURE can be the result of a signal adjustment or conversion[3] and so the mode of operation is called the ADJUSTED MODE. For example, an infrared PROBE can be placed in an ear canal but the digital display (OUTPUT TEMPERATURE) indicates an estimated sublingual temperature of the PATIENT. ADJUSTED MODE CLINICAL THERMOMETERS compensate for limitations of DIRECT MODE CLINICAL THERMOMETERS by using signal processing algorithms to estimate temperature from measured values, though there is often a corresponding reduction in CLINICAL ACCURACY. This particular standard requires both clinical VALIDATION and laboratory VERIFICATION for all types of ADJUSTED MODES.

Examples of two common types of ADJUSTED MODES follow.

The first type is the case of a predictive intermittent CLINICAL THERMOMETER that displays an OUTPUT TEMPERATURE before reaching thermal equilibrium, so the displayed OUTPUT TEMPERATURE is an estimate of the "would-be" equilibrium temperature by computation, therefore generally reducing the measurement time. An example of this type is a contact skin CLINICAL THERMOMETER such as a zero-heat flow CLINICAL THERMOMETER. This type of ADJUSTED MODE is used to reduce the measurement time, e.g. from minutes to several seconds. It takes about 5 min for a sublingual CLINICAL THERMOMETER, and about 10 min for an axillary (under the armpit) CLINICAL THERMOMETER to achieve thermal equilibrium, while a predictive intermittent CLINICAL THERMOMETER can produce an OUTPUT TEMPERATURE in less than 20 s.

For a predictive intermittent CLINICAL THERMOMETER, the rate of change of the SENSOR'S output is measured and used to predict (anticipate) the final equilibrium temperature which is never reached during the time of measurement.[39] Figure AA.101 illustrates this situation. After the SENSOR is thermally coupled to the MEASURING SITE (time t_1), the SENSOR'S temperature gradually rises from temperature T_a. Before reaching thermal equilibrium T_m (time t_3), the CLINICAL THERMOMETER predicts the equilibrium temperature of the SENSOR (temperature T_R at time t_2). The time to achieve thermal equilibrium depends on various factors, including: the MEASURING SITE, the CLINICAL THERMOMETER design and the ambient temperature. To calculate an equilibrium temperature before establishing thermal equilibrium, several data points of the time-dependent temperature change of the SENSOR are taken to calculate or estimate the OUTPUT TEMPERATURE.



Key

T_a is the ambient temperature
T_m is the MEASURING SITE temperature
T_R is the REFERENCE BODY SITE temperature
t_1 is the time of thermal coupling
t_2 is the time when the temperature at the MEASURING SITE is estimated
t_3 is the time when achieving thermal equilibrium could have been reached

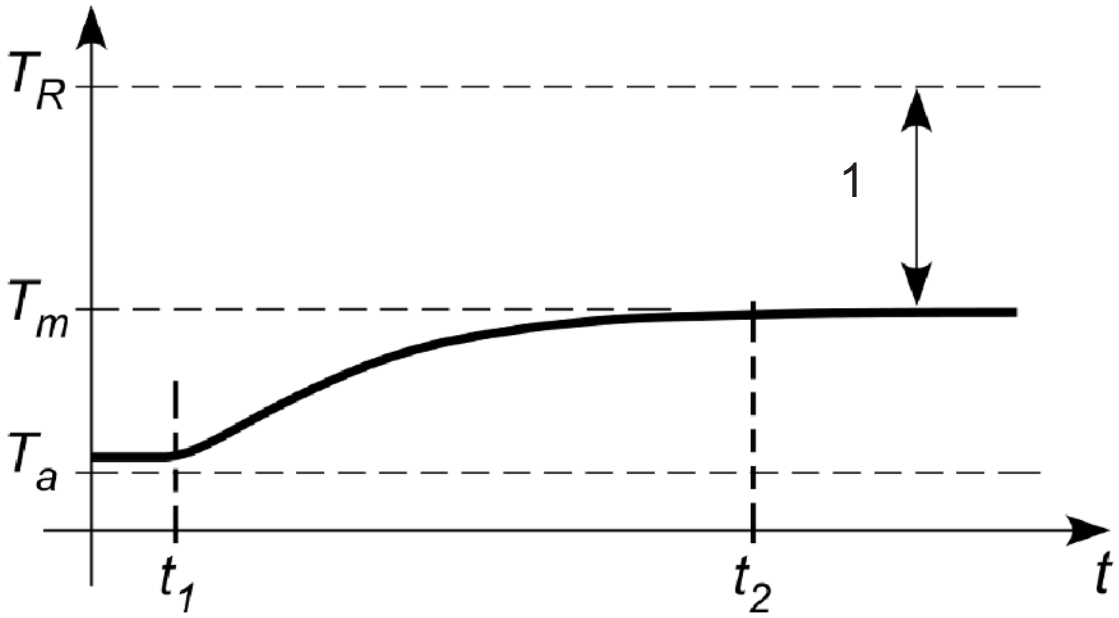
NOTE The MEASURING SITE is the same as the REFERENCE BODY SITE.

Figure AA.101 — Example of temperature adjustment for a predictive intermittent CLINICAL THERMOMETER

The second type is a CLINICAL THERMOMETER where the OUTPUT TEMPERATURE is not referenced to the actual MEASURING SITE (i.e., the REFERENCE BODY SITE is different than the MEASURING SITE). An example of this type of CLINICAL THERMOMETER is a constant-heat flow CLINICAL THERMOMETER such as a sublingual equilibrium CLINICAL THERMOMETER or a radiance ear canal CLINICAL THERMOMETER that estimates the temperature at a different body site by calculation. This type of ADJUSTED MODE performs a positional dependent adjustment or

physiological offset with the aim of providing for convenient temperature measurement of a desired body site that is different from the MEASURING SITE.

A body site adjustment uses either a constant offset or a more complex algorithm to modify the MEASURING SITE temperature to account for the natural anatomical, physiological and environmental factors to give an estimate of the REFERENCE BODY SITE temperature. For example, a sublingual temperature (underneath the tongue is the MEASURING SITE) can be used to estimate the rectal temperature (the rectum is the REFERENCE BODY SITE) by subtracting a fixed offset. Figure AA.102 illustrates this situation. After the SENSOR is thermally coupled to the MEASURING SITE (time t_1 is when it is placed under the tongue) the SENSOR'S temperature gradually rises until it reaches thermal equilibrium with the MEASURING SITE (time t_2 and SENSOR temperature T_m). The OUTPUT TEMPERATURE of the desired body site, T_R, is then calculated or estimated from the measured temperature at the MEASURING SITE, T_m, using the algorithm of the CLINICAL THERMOMETER which produces an adjustment, 1.



Key

1 temperature adjustment or the offset between the MEASURING SITE temperature and the estimate of the REFERENCE BODY SITE temperature

T_a is the ambient temperature

T_m is the MEASURING SITE temperature

T_R is the REFERENCE BODY SITE temperature

t_1 is the time of thermal coupling

t_2 is the time when the temperature at the MEASURING SITE is measured

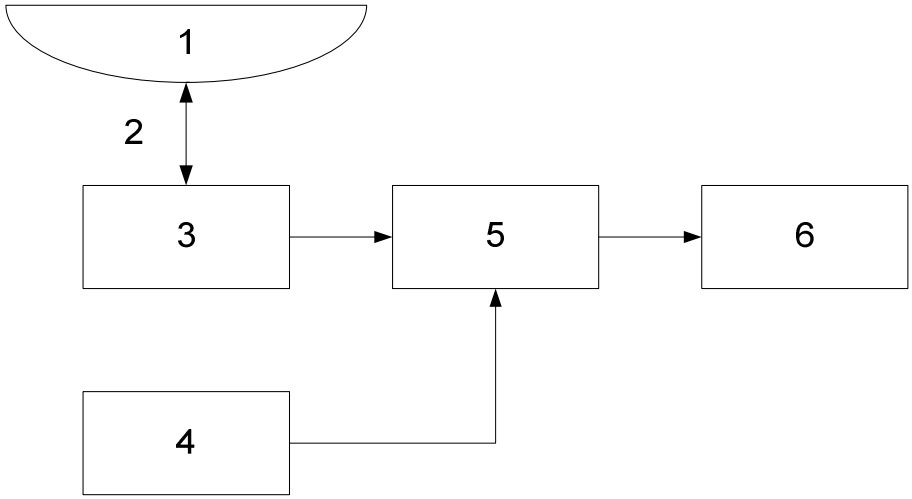
NOTE The MEASURING SITE is different than the REFERENCE BODY SITE.

Figure AA.102 — Example of temperature estimation for a different body site

AA.201.3.206 CLINICAL THERMOMETER

Any CLINICAL THERMOMETER (see Figure AA.103) contains at least two essential components: a SENSOR (for example a thermistor or a thermopile) and an output means (for example a digital display, speaker or printer). A SENSOR is usually incorporated inside or positioned near the PROBE. The PROBE can be attached directly to the enclosure of a CLINICAL THERMOMETER or connected to it by a cable. To measure temperatures, the PROBE is placed so that the SENSOR is thermally coupled to the MEASURING SITE. The SENSOR converts thermal energy into an electrical signal from which an output representation of the temperature is derived. Other auxiliary

components and a signal processing circuit can also be included. The auxiliary components and processing circuit can include the ambient temperature SENSOR, optical components, microcontroller, power supply and other components. A microcontroller uses software that processes the signals that are received from the SENSOR according to an algorithm that displays OUTPUT TEMPERATURE in the appropriate format.



Key

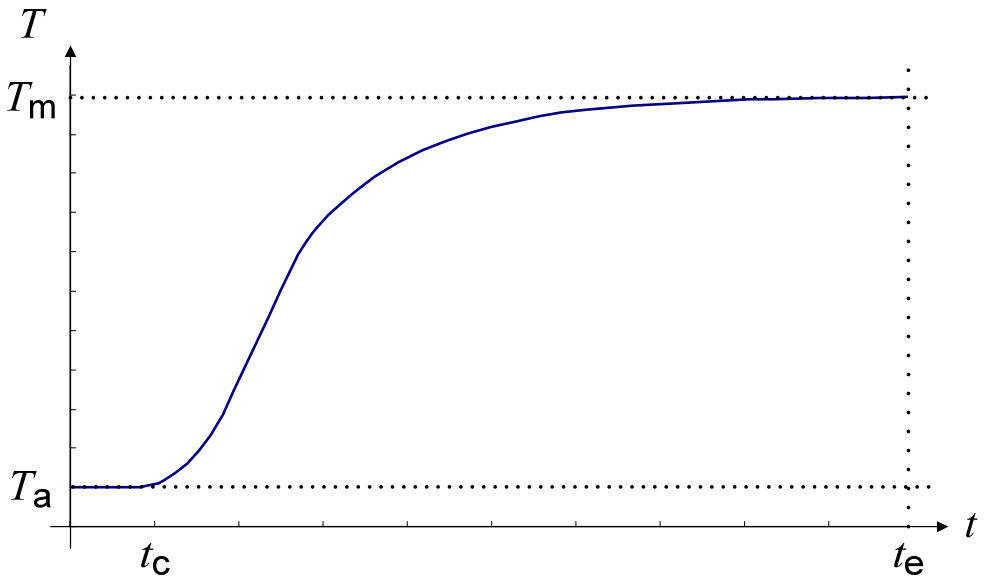
1 MEASURING SITE
2 thermal coupling (contact or non-contact)
3 SENSOR
4 auxiliary components
5 processing circuit
6 output means that indicates OUTPUT TEMPERATURE

Figure AA.103 — General structure of a CLINICAL THERMOMETER

AA.201.3.207 DIRECT MODE

A DIRECT MODE CLINICAL THERMOMETER (or the TEST MODE of an ADJUSTED MODE CLINICAL THERMOMETER) is a CLINICAL THERMOMETER whose OUTPUT TEMPERATURE is intended to represent the true temperature of the MEASURING SITE or object which is thermally coupled to the SENSOR. In other words, the actual temperature detected by the SENSOR is displayed as the OUTPUT TEMPERATURE; whatever is measured is indicated. The operation of a zero-heat flow CLINICAL THERMOMETER, which is also called an *equilibrium* CLINICAL THERMOMETER, relies on a thermal equilibrium between the SENSOR and the MEASURING SITE. This means that there is negligible heat flow between the MEASURING SITE and the SENSOR. In other words, the SENSOR and the MEASURING SITE are in thermal equilibrium or have nearly the same temperature (see Figure AA.104). Examples of an equilibrium CLINICAL THERMOMETER include a sublingual "pencil" CLINICAL THERMOMETER and a pulmonary artery CLINICAL THERMOMETER. An equilibrium CLINICAL THERMOMETER can take a significant period of time to reach thermal equilibrium and display its OUTPUT TEMPERATURE. For example, it takes approximately 5 min, for a "pencil" sublingual CLINICAL THERMOMETER, and about 10 min for an axillary (under the armpit) CLINICAL THERMOMETER to achieve thermal equilibrium.

A REFERENCE THERMOMETER that is employed in a laboratory for measuring the temperature of a REFERENCE TEMPERATURE SOURCE (for example, a water bath) for determining the laboratory performance of a CLINICAL THERMOMETER is also a DIRECT MODE equilibrium type. However, it is not a CLINICAL THERMOMETER and is not intended for use on PATIENTS.



Key

T_a is the ambient temperature

T_m is the MEASURING SITE temperature

t_c is the time of thermal coupling

t_e is the time of achieving thermal equilibrium

Figure AA.104 — Thermal response of a zero-heat flow CLINICAL THERMOMETER

AA.201.3.219 REFERENCE BODY SITE

A CLINICAL THERMOMETER measures and indicates temperatures of a specific organ or area of a PATIENT**'s** body called a "*body site*". The site where the temperature is actually measured (MEASURING SITE) and the site for which the temperature is indicated (REFERENCE BODY SITE) are not necessarily the same. For example, a measurement can be made sublingually, while the OUTPUT TEMPERATURE indicates a temperature that corresponds to the rectum. Thus, two types of "*body sites*" should be considered.

— The MEASURING SITE is a place on or inside the body of the PATIENT where the PROBE is positioned and to which the SENSOR is thermally coupled.

— The REFERENCE BODY SITE is the part of the body of the PATIENT whose temperature is directly measured or calculated and indicated by the output means of a CLINICAL THERMOMETER.

Many parts of a PATIENT can be the subject of temperature measurement for the purpose of diagnosing and monitoring. These purposes can include detection of fever, detection of life-threatening situations (e.g. malignant hyperthermia, sepsis), determination of the moment of ovulation, monitoring of a physiological response to various medications and procedures, effects of exercise and physical work, a mental state and many other applications. Temperatures can be measured from internal organs or from the skin surface. Either location can provide valuable information about blood perfusion and transcutaneous temperatures, such as those of the underlying arteries and veins.

For the purpose of detecting fever, body temperatures have been historically measured by contact CLINICAL THERMOMETERS in the sublingual, rectal, or axillary (under the armpit) MEASURING SITES which were the same as the REFERENCE BODY SITES. However, most externally accessible MEASURING SITES have not represented the body core temperature with a specific quantitative relationship. Thus, during surgical procedures and intensive care, temperatures often are measured by invasive PROBES in recognized core temperature MEASURING SITES (e.g. pulmonary artery, distal oesophagus and urinary bladder). These PROBES are normally combined with

invasive devices, for example a Foley catheter. Although this particular standard does not deny the use of new REFERENCE BODY SITES, new REFERENCE BODY SITES should be scientifically and clinically evaluated for a particular medical purpose. For ADJUSTED MODE CLINICAL THERMOMETERS, this particular standard does require clinical VALIDATION with an existing REFERENCE CLINICAL THERMOMETER. This requirement means that the OUTPUT TEMPERATURE of a new CLINICAL THERMOMETER has to reference a REFERENCE BODY SITE utilized by an existing VALIDATED CLINICAL THERMOMETER.

AA.201.4.3.101 Additional requirements for ESSENTIAL PERFORMANCE

CLINICAL THERMOMETERS span the range from invasive ME EQUIPMENT with sophisticated ALARM SYSTEMS that continually monitor critically ill PATIENTS to simple, inexpensive home healthcare environment ME EQUIPMENT. Every CLINICAL THERMOMETER measures or estimates the temperature of a REFERENCE BODY SITE for the purpose of diagnosing or monitoring. These purposes can be the detection of fever, determination of the moment of ovulation, monitoring of the physiological response to medication and procedures, detection of life-threatening situations (e.g. malignant hyperthermia, sepsis) and many other applications.

This standard considers it an unacceptable RISK for a CLINICAL THERMOMETER to present an OUTPUT TEMPERATURE that is not accurate without indicating that it is not accurate. Methods of indicating this degraded performance include generating a TECHNICAL ALARM CONDITION or not providing an OUTPUT TEMPERATURE. Additionally, to allow for affordable home healthcare CLINICAL THERMOMETERS, this standard permits the permissible operating temperature range to be marked on the CLINICAL THERMOMETER.

AA.201.12.2.101 Additional requirements for USABILITY

CLINICAL THERMOMETERS that are intended for home healthcare use (e.g., the PATIENT can be the OPERATOR) need to be readable by OPERATORS that have impaired vision. Additionally, CLINICAL THERMOMETERS that utilize a segmented display need an effective functional test that ensures that all segments are functioning. This ensures that the OPERATOR can distinguish between numbers such as 4 and 9, 5 and 6, or 1 and 7.

AA.201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

The radiated immunity environment during PATIENT transport outside the healthcare facility (e.g. land and air ambulances) is harsher than the typical environment in a healthcare facility. The main cause of this difference is the presence of multiple two-way radio communication systems that intentionally radiate electromagnetic energy. In both of these environments, ME EQUIPMENT meeting the requirements of IEC 60601-1-2:2007 is adequately protected from unintentional sources of electromagnetic interference. The additional testing needed to qualify ME EQUIPMENT for the transport environment outside the healthcare facility needs to address only this additional threat.

Two-way communication devices are used to transmit both voice and PATIENT data. Experience has shown that typical field strengths[22] measured in this environment can be as high as 20 V/m. Voice and PATIENT data typically have modulation bandwidths that exceed 1 kHz with a centre-point of voice modulation of 1 kHz. The committee chose a single test point to represent the typical information modulation band. A signal with an 80 % amplitude modulation at 1 kHz was chosen, and is consistent with the base radiated immunity standard IEC 61000-4-3 [53] that also uses 80 % amplitude-modulated signal at 1 kHz. A 20 V_{rms}/m 80 % amplitude-modulated signal has a peak-to-peak amplitude of 90,5 V.

AA.201.101.1 General test requirements

An ultimate goal of a CLINICAL THERMOMETER is to assess the true temperature of a REFERENCE BODY SITE. Thus, CLINICAL ACCURACY of such a CLINICAL THERMOMETER can only be assessed by comparing its OUTPUT TEMPERATURE with that of another thermometer (REFERENCE THERMOMETER) when temperatures are taken concurrently from the same object or the same subject. The methods of assessment are not the same for DIRECT MODE and ADJUSTED MODE CLINICAL THERMOMETERS. They also can be different for CLINICAL THERMOMETERS with invasive and non-invasive PROBES.

For all CLINICAL THERMOMETERS whose PROBES have negligible thermal contact with the environment (zero-heat flow thermometers) and whose OUTPUT TEMPERATURES are not adjusted, a laboratory assessment of performance is sufficient. This is done by performing temperature measurements with the CLINICAL

THERMOMETER by employing a REFERENCE TEMPERATURE SOURCE and comparing the OUTPUT TEMPERATURE of the CLINICAL THERMOMETER with the temperature of the REFERENCE TEMPERATURE SOURCE. This laboratory assessment is described in Clause 201.101.

For all other CLINICAL THERMOMETERS (ADJUSTED MODE), additional clinical VALIDATION with subjects is required, because the measured temperature is modified to indicate the OUTPUT TEMPERATURE. The modification is a function of the physiological and anatomical properties of an average subject as well as of the environmental conditions. Thus, to assess the effectiveness of such a CLINICAL THERMOMETER it is compared with another CLINICAL THERMOMETER whose CLINICAL ACCURACY has already been established (i.e. a REFERENCE CLINICAL THERMOMETER). The CLINICAL ACCURACY VALIDATION is described in Clause 201.102.

Table AA.101 summarizes the types of required testing for certain CLINICAL THERMOMETERS.

For some CLINICAL THERMOMETERS, the ACCOMPANYING DOCUMENT indicates the use of a new PROBE COVER for every new measurement. The purpose of the PROBE COVER is to minimize the RISK of cross-contamination between PATIENTS and to prevent soiling of the components of the CLINICAL THERMOMETER (e.g. by dust, feces or ear wax adhering to the PROBE). Additionally, improper application of the PROBE COVER to the CLINICAL THERMOMETER critically affects the measurement result and care should be taken to properly mount or apply the PROBE COVERS to CLINICAL THERMOMETERS according the procedure indicated in the ACCOMPANYING DOCUMENT.

Table AA.101 — Required tests for CLINICAL THERMOMETERS

Type of CLINICAL THERMOMETER	LABORATORY ACCURACY verification		CLINICAL ACCURACY validation		
	RATED OUTPUT RANGE	RATED EXTENDED OUTPUT RANGE[a]	CLINICAL BIAS	LIMITS OF AGREEMENT	CLINICAL REPEATABILITY
Intermittent or continuous CLINICAL THERMOMETER in DIRECT MODE: for example, a thermometer with invasive catheter PROBE; or a “pencil” contact thermometer for which the MEASURING SITE and REFERENCE BODY SITE is the same, e.g. sublingual, rectal, axillary (under armpit).	✓	✓	no	no	no
Intermittent CLINICAL THERMOMETER in ADJUSTED MODE: for example, a “pencil” predictive thermometer for which the MEASURING SITE and REFERENCE BODY SITE is not the same e.g. sublingual, rectal, axillary (under armpit); an infrared thermometer for which the MEASURING SITE is skin or the ear canal (tympanic membrane); or a contact thermometer for which the MEASURING SITE is skin with a different REFERENCE BODY SITE.	✓	✓	✓	✓	✓
Continuous CLINICAL THERMOMETER in ADJUSTED MODE: for example, a contact thermometer for which the MEASURING SITE and REFERENCE BODY SITE are different.	✓	✓	✓	✓	no

[a] If any.

The disposable PROBE COVERS for some radiance (infrared) ear CLINICAL THERMOMETERS (IRETs) are made from a polymeric material. The PROBE COVER acts as a relatively strong filter in the mid infrared spectral range. Consistent thermal and optical characteristics of these disposable PROBE COVERS influence the overall accuracy of an IRET.[44] Disposable PROBE COVERS for CLINICAL THERMOMETERS utilizing predictive algorithms can also affect performance. Minor variations in thickness or thermal coefficient influence the accuracy of

these CLINICAL THERMOMETERS. The variability of the performance of PROBE COVERS influences the overall uncertainty and has to be considered carefully. These can be important considerations for any CLINICAL THERMOMETERS.

AA.201.101.2 LABORATORY ACCURACY

The environmental conditions of ambient temperature and relative humidity can affect the performance of a CLINICAL THERMOMETER. Within the RATED range of such conditions, the CLINICAL THERMOMETER is required to meet the requirements while being tested in a laboratory. Table AA.102 provides suggested combinations of REFERENCE TEMPERATURE SOURCE temperature, operating temperature and relative humidity at which the CLINICAL THERMOMETER is tested.

Continuous CLINICAL THERMOMETERS are intended to monitor temperatures over time. They do not operate in the ADJUSTED MODE and they are well coupled to the MEASURING SITE. They have a CLINICAL ACCURACY that is equivalent to their LABORATORY ACCURACY. As a result, such CLINICAL THERMOMETERS are permitted to have a larger LABORATORY ACCURACY specification.

Table AA.102 — Example combinations of operating conditions and REFERENCE temperature for testing the LABORATORY ACCURACY

REFERENCE temperature		
Upper limit of RATED OUTPUT RANGE –0,5 °C ± 0.5 °C	Midpoint of RATED OUTPUT RANGE ± 1 °C	Lower limit of RATED OUTPUT RANGE + 0,5 °C ± 0.5 ºC
Operating conditions		
Upper limit of RATED ambient temperature range –0,5 °C ± 0.5 °C Upper limit of RATED humidity range –5 % ± 5 %	Upper limit of RATED ambient temperature range –0,5 °C ± 0.5 °C Upper limit of RATED humidity range –5 % ± 5 %	Upper limit of RATED ambient temperature range –0,5 °C ± 0.5 °C Upper limit of RATED humidity range –5 % ± 5 %
Upper limit of RATED ambient temperature range –0,5 °C ± 0.5 °C Lower limit of RATED humidity range +5 % ± 5 %	Upper limit of RATED ambient temperature range –0,5 °C ± 0.5 °C Lower limit of RATED humidity range +5 % ± 5 %	Upper limit of RATED ambient temperature range –0,5 °C ± 0.5 °C Lower limit of RATED humidity range +5 % ± 5 %
Midpoint of RATED ambient temperature range ± 5 °C Midpoint of RATED ambient humidity range ± 20 %	Midpoint of RATED ambient temperature range ± 5 °C Midpoint of RATED ambient humidity range ± 20 %	Midpoint of RATED ambient temperature range ± 5 °C Midpoint of RATED ambient humidity range ± 20 %
Lower limit of RATED ambient temperature range +0,5 °C ± 0.5 °C Upper limit of RATED humidity range –5 % ± 5 %	Lower limit of RATED ambient temperature range +0,5 °C ± 0.5 °C Upper limit of RATED humidity range –5 % ± 5 %	Lower limit of RATED ambient temperature range +0,5 °C ± 0.5 °C Upper limit of RATED humidity range –5 % ± 5 %
Lower limit of RATED ambient temperature range +0,5 °C ± 0.5 °C Lower limit of RATED humidity range +5 % ± 5 %	Lower limit of RATED ambient temperature range +0,5 °C ± 0.5 °C Lower limit of RATED humidity range +5 % ± 5 %	Lower limit of RATED ambient temperature range +0,5 °C ± 0.5 °C Lower limit of RATED humidity range +5 % ± 5 %

a)

The REFERENCE TEMPERATURE SOURCE is used to check the LABORATORY ACCURACY of the CLINICAL THERMOMETER. The largest permitted LABORATORY ACCURACY is 0,2 °C or 0,3 °C for a continuous CLINICAL THERMOMETERS that does not operate in the ADJUSTED MODE. In VERIFICATION, the expanded uncertainty of the measurement is usually considered to be small enough if it does not exceed 1/3 of the LABORATORY ACCURACY.[48] In the case of CLINICAL THERMOMETERS, this requires an uncertainty of the REFERENCE TEMPERATURE SOURCE at a coverage factor k = 2 of 0,2 °C/3 = 0,07 °C.

AA.201.101.3 Time response for a continuous CLINICAL THERMOMETER

The ability of a continuous CLINICAL THERMOMETER to track changing PATIENT temperature can be assessed by its response to a rapid change in the REFERENCE TEMPERATURE SOURCE. Depending on the type of a continuous PROBE, the REFERENCE TEMPERATURE SOURCE can be a FLUID BATH (water bath, e.g.), a BLACKBODY, or another type of heat source, for example, a thermally controlled plate. The test is performed by quickly transferring a PROBE from one REFERENCE TEMPERATURE SOURCE to another REFERENCE TEMPERATURE SOURCE that has a different temperature. The faster the OUTPUT TEMPERATURE approaches the REFERENCE TEMPERATURE SOURCE temperature, the better the temperature tracking ability of a continuous CLINICAL THERMOMETER.

Previous standards for CLINICAL THERMOMETERS required a transient response test for intermittent CLINICAL THERMOMETERS. These tests do not appear in this particular standard because ADJUSTED MODE CLINICAL ACCURACY tests will uncover problems with response time. If the CLINICAL THERMOMETER is slow to respond relative to the time disclosed in the instructions for use, that source of error would appear in the resulting CLINICAL BIAS with associated LIMITS OF AGREEMENT and/or CLINICAL REPEATABILITY.

AA.201.102 CLINICAL ACCURACY VALIDATION

While laboratory testing is sufficient for a DIRECT MODE CLINICAL THERMOMETER, it is not enough for an ADJUSTED MODE CLINICAL THERMOMETER because adjustment algorithms are specific for the anatomical and physiological properties of PATIENTS and the environment. These properties cannot be closely simulated by any known laboratory REFERENCE TEMPERATURE SOURCE, setting or instrument. Thus, the CLINICAL ACCURACY of an ADJUSTED MODE CLINICAL THERMOMETER is required to be additionally VALIDATED with actual subjects (PATIENTS). Since all subjects are different, statistical methods are employed to compare the OUTPUT TEMPERATURES of the CLINICAL THERMOMETER under test (TUT) for the REFERENCE BODY SITE with those of a REFERENCE CLINICAL THERMOMETER (RCT) whose OUTPUT TEMPERATURES represent the same REFERENCE BODY SITE as the TUT.

The RCT PROBE might not necessarily be placed at the same MEASURING SITE as the TUT PROBE. Moreover, they both can indicate temperatures of a third site, the REFERENCE BODY SITE. For example, the TUT is a forehead skin CLINICAL THERMOMETER (the TUT MEASURING SITE is forehead skin), the RCT is an oral CLINICAL THERMOMETER (the RCT MEASURING SITE is sublingual) and they both output core temperatures (REFERENCE BODY SITE is core). The RCT CLINICAL ACCURACY in representing the REFERENCE BODY SITE temperature was previously VALIDATED. It has an acceptable value of CLINICAL BIAS that carries an acceptable diagnostic RISK. If either the TUT or the RCT uses disposable PROBE COVERS, a new PROBE COVER is used for each new measurement. This permits the test to include the PROBE COVER tolerances in the VERIFICATION of the total CLINICAL ACCURACY.

Hence, performance of a TUT in ADJUSTED MODE is assessed in two steps (see Table AA.101).

1) VERIFICATION of a LABORATORY ACCURACY as described in Clause 201.101.

2) VALIDATION of CLINICAL ACCURACY while taking temperatures from a sufficiently large group of subjects which is described in Clause 201.102.

AA.201.102.2 Human subject population requirements

There is no known data that would suggest that the CLINICAL ACCURACY of a CLINICAL THERMOMETER in an ADJUSTED MODE is affected by the gender or race of a PATIENT. However, the age of a PATIENT is a known and important factor.[6][30] Thermal control in humans develops as the individual grows. Besides, with age organs change in size, tissue texture, blood perfusion and other properties. All these can affect the adjustment algorithms. When assessing CLINICAL ACCURACY, selection of subjects for the test needs to include a sufficient number of subjects with the ages for which the TUT is intended. This particular standard recommends that four age groups be tested (see Table 201.102).

If a CLINICAL THERMOMETER is intended for a subject of any age, all four groups are required to be tested separately. Generally, it is preferable that ages of subjects are distributed within a group as uniformly as possible. The total number of valid subjects in any group is required to be no less than 35 and the total number of the tested subjects is required to be at least 105. However, if a particular TUT is not intended for all ages, the total number of tested subjects is still required to be at least 105. For example, if a basal CLINICAL THERMOMETER is intended for the ovulating females, it would be tested only with Group C. The total number of subjects in that group is still required to be at least 105. However, there is no need to test too young or too old female subjects. For that particular type of CLINICAL THERMOMETER, the subjects should be females between 15 and 50 years of age and there is no need to test older or younger subjects.

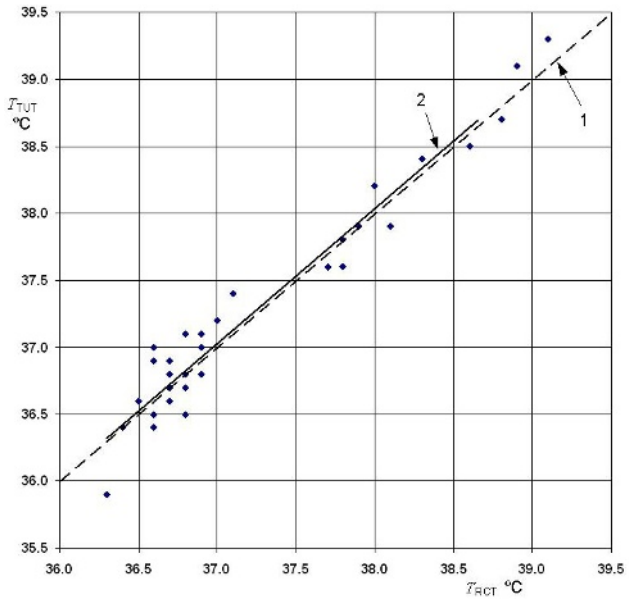
For VALIDATION of an ADJUSTED MODE continuous CLINICAL THERMOMETER no separation of age groups is required. However, the ages of the subjects should be uniformly distributed within the tested population. The total number of tested subjects is still required to be at least 105.

AA.201.102.3 CLINICAL BIAS calculation

To evaluate a CLINICAL BIAS, a sufficiently large number of temperature pairs should be taken by two thermometers - the CLINICAL THERMOMETER under test (TUT) and the REFERENCE CLINICAL THERMOMETER (RCT) from multiple subjects with at least one pair of OUTPUT TEMPERATURES per subject.

Since three consecutive temperatures are taken from the MEASURING SITE by the TUT, only the first one is used in computation of the CLINICAL BIAS, because in clinical practice typically only one temperature measurement is performed.

Figure AA.105 shows a data plot for pairs of temperatures taken by the TUT and the RCT. For an ideal equality, all data points should fall onto a 45° line of equality. In reality, the data points might scatter around a shifted line that could be above or below the ideal line of equality. Moreover, the line might not be a 45° line and could even be curved. The shift of the line is measured by the value of the average CLINICAL BIAS which shows the tendency of the TUT to overestimate or underestimate temperatures as compared with the RCT.



Key

T_{TUT} is the OUTPUT TEMPERATURE of the TUT

T_{RCT} is the OUTPUT TEMPERATURE of the CRT

1 line of equality

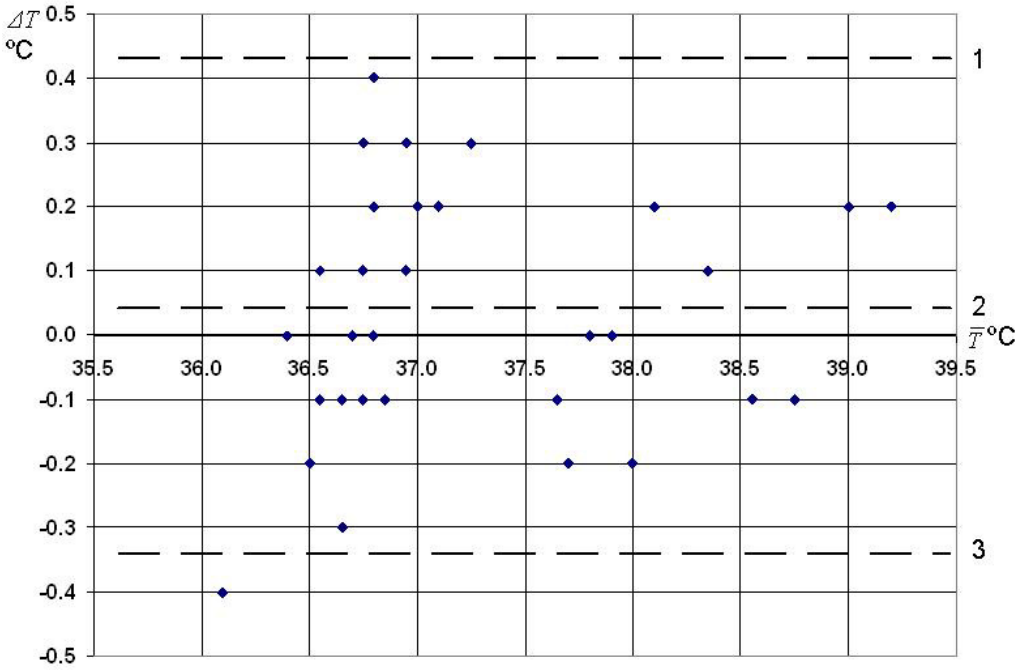
2 linear regression line

Figure AA.105 — Example of a comparison plot for TUT and RCT

AA.201.102.4 LIMITS OF AGREEMENT calculation

Dispersion of OUTPUT TEMPERATURES around the CLINICAL BIAS can be estimated by the standard deviation σ_d of the temperature differences between the CLINICAL THERMOMETER under test (TUT) and the RCT as measured from multiple subjects. For a graphical illustration and analysis, it is convenient to plot the differences, ΔT, against the average values of OUTPUT TEMPERATURES from the TUT and the RCT, i.e. $(T_{TUT} + T_{RCT})/2$, as shown in Figure AA.106.

If the differences are normally distributed, it can be expected that about 95 % of them will fall in the range of $\bar{d} \pm 2 \times \sigma_d$. This range is called the “95 % limits of the agreement”. This particular standard defines LIMITS OF AGREEMENT as $2 \times \sigma_d$. It characterizes the range within which most differences between the OUTPUT TEMPERATURES by the TUT and the RCT lie.



Key

ΔT is the temperature differences between the CLINICAL THERMOMETER under test (TUT) and the RCT

$\bar{T}$ is the average of OUTPUT TEMPERATURES from the TUT and the RCT

1 $\bar{d} + 2 \times \sigma_d$

2 $\bar{d}$ is the mean difference between OUTPUT TEMPERATURES from the TUT and the RCT

3 $\bar{d}$ - 2 x σ_d

Figure AA.106 — Example of a Bland-Altman Plot of the temperature difference (TUT minus RCT) versus the average OUTPUT TEMPERATURES of two thermometers

Table AA.103 exemplifies results of a CLINICAL ACCURACY test, with the total number of PATIENTS in the group n = 36, both febrile and afebrile. Three sequential OUTPUT TEMPERATURES from each PATIENT are measured and indicated by a TUT as t_1, t_2 and t_3. Note that only one TUT temperature t_1 was taken from febrile PATIENTS (subjects numbers 3 and 5). The bias and standard deviation were calculated from the temperature differences (t_1 - t_{RCT}) as +0,07 °C and 0,37 °C respectively. The bias is acceptable, although the LIMITS OF AGREEMENT (0,44 °C) are on the high side they could be considered by some to be clinically acceptable. The CLINICAL REPEATABILITY of all subjects, other than febrile subjects less than 5 years old, as computed using Equation (5) is σ_r = 0,23 °C. This number appears to be reasonable. As a result of the test, the TUT could be considered a clinically useful thermometer.

A **TUT** would be considered clinically equivalent to the RCT if the calculated LIMITS OF AGREEMENT are not clinically important and would not lead to unmanageable diagnostic errors. A bias, $\bar{d}$, that is consistent over all tested CLINICAL THERMOMETERS is a systematic error and generally can be adjusted. However, a large standard deviation, s_d, and hence widely spaced LIMITS OF AGREEMENT are a much more serious issue.

Table AA.103 — Example of CLINICAL ACCURACY VALIDATION test results

PATIENT	T_1 °C	T_2 °C	T_3 °C	T_{RCT} °C	$T_1 - T_{RCT}$ °C	σ_j °C
1	36,5	36,7	36,2	36,4	0,1	0,25
2	37,1	37,0	36,8	36,9	0,2	0,15
3	39,9			39,3	-0,4	
4	35,8	35,9	36,2	35,8	0,0	0,21
5	38,2			38,0	0,2	
6	37,4	37,1	36,9	37,1	0,3	0,25
…	…	…	…	…	…	…
34	36,7	36,5	36,4	36,5	0,2	0,15
35	36,6	36,9	36,7	36,8	-0,2	0,15
36	36,1	36,3	36,3	36,0	0,1	0,12
Bias, $\overline{d}$					0,07	
Standard Deviation					0,22	
LIMITS OF AGREEMENT, L_A					0,44	
CLINICAL REPEATABILITY, σ_r						0,23

AA.201.102.5 CLINICAL REPEATABILITY calculation

CLINICAL REPEATABILITY (sometimes called the perceived accuracy) is a measure of the consistency of repeated measurements with identical operating conditions when temperatures are taken within short time intervals from the same MEASURING SITE of the same subject by the same OPERATOR with the same intermittent CLINICAL THERMOMETER. This characteristic is applicable only to intermittent CLINICAL THERMOMETERS. To determine the CLINICAL REPEATABILITY, three OUTPUT TEMPERATURES ($t_{1,j}$, $t_{2,j}$, and $t_{3,j}$) are taken from each subject by the CLINICAL THERMOMETER under test (TUT). No RCT is required as the TUT OUTPUT TEMPERATURES are compared with themselves. Reasonable time delays between the measurements are necessary to minimize effects of cooling the MEASURING SITE by the PROBE and thermal drifts in the PROBE. The ACCOMPANYING DOCUMENT recommends the minimum time between measurements (the highest possible rate of taking temperatures) at the MEASURING SITE. The CLINICAL REPEATABILITY does not show the CLINICAL ACCURACY of the TUT, only the consistency of the OUTPUT TEMPERATURES.

CLINICAL REPEATABILITY is a pooled standard deviation of triplicate measurements over the population of subjects, other than febrile subjects less than 5 years old.

AA.201.103 PROBES, PROBE CABLE EXTENDERS and PROBE COVERS

PROBES, PROBE CABLE EXTENDERS and PROBE COVERS are as important in establishing the safety and accuracy of the complete CLINICAL THERMOMETER as is the indicating unit and any software algorithms. This clause establishes that the MANUFACTURER of the PROBE, PROBE CABLE EXTENDER or PROBE COVER (including a MANUFACTURER of a REPROCESSED PROBE, PROBE CABLE EXTENDER or PROBE COVER) is responsible not only for the separately testable properties (such as biocompatibility) of the PROBE, PROBE CABLE EXTENDER or PROBE COVER itself, but also for the affected combined properties (such as accuracy, electromagnetic compatibility, and electrical safety) of the CLINICAL THERMOMETERS that the MANUFACTURER specifies that the PROBE, PROBE CABLE EXTENDER or PROBE COVER can be used with. As an example of a possible effect of REPROCESSING on biocompatibility, glutaraldehyde sterilization of silicone rubber materials can result in impregnation of the material with solvent which, if not sufficiently removed, by subsequent processing can cause a chemical burn when that PROCESS is not described (and therefore VALIDATED) in the ACCOMPANYING DOCUMENTS.[6][7][8][9]

Annex BB
(informative)

REFERENCE TEMPERATURE SOURCE

BB.1 Type of CLINICAL THERMOMETER

BB.1.1 For contact CLINICAL THERMOMETER

BB.1.1.1 REFERENCE THERMOMETER

REFERENCE THERMOMETER, with an expanded uncertainty (coverage factor $k = 2$) in OUTPUT TEMPERATURE not greater than $\pm$ 0,02 °C is used to determine the temperature of the FLUID BATH. Its calibration is required to be traceable to national measurement standards.

NOTE The definition of the coverage factor "*k*" can be found in ISO/IEC Guide 99[2].

BB.1.1.2 FLUID BATH

FLUID BATH, well regulated and stirred and containing at least 5 l in volume is used to establish reference temperatures over the measuring range. It should be controlled to have a suitable temperature stability of better than $\pm$ 0,02 °C over the RATED measuring range of temperature of the CLINICAL THERMOMETER to be tested. It should have a temperature gradient of not greater than $\pm$ 0,01 °C within its working space at any temperature used.

BB.1.2 For non-contact CLINICAL THERMOMETER

BB.1.2.1 REFERENCE THERMOMETER and FLUID BATH described in BB.1.1.1 and BB.1.1.2.

BB.1.2.2 BLACKBODY cavity with an emissivity close to one.

References [3], [4] and [5] have examples of suitable designs of a BLACKBODY radiator.

BB.2 Uncertainty of a REFERENCE TEMPERATURE SOURCE

Total expanded uncertainty of a REFERENCE TEMPERATURE SOURCE, U_{RTS}, is calculated with Equation (B.1).

$$U_{\mathrm{RTS}} = \sqrt{U_{\mathrm{RT}}^2 + U_{\mathrm{stab}}^2 + U_{\mathrm{hom}}^2 + U_{\varepsilon}^2 + U_{\Delta \mathrm{T}}^2} \qquad \text{(B.1)}$$

where

U_{RT} is an expanded uncertainty of the REFERENCE THERMOMETER;

U_{stab} is an expanded uncertainty of the temperature stability of a REFERENCE TEMPERATURE SOURCE;

U_{hom} is an expanded uncertainty of the temperature homogeneity (uniformity) of the REFERENCE TEMPERATURE SOURCE;

U_{ε} is an expanded uncertainty of a REFERENCE TEMPERATURE SOURCE due to uncertainty of emissivity of the BLACKBODY;

$U_{\Delta \mathrm{T}}$ is an expanded uncertainty due to the temperature difference between the BLACKBODY REFERENCE THERMOMETER and the inner surface temperature of the BLACKBODY.

NOTE 1 The uncertainty components U_{ε} and $U_{\Delta T}$ are only applicable when a BLACKBODY is utilized.

NOTE 2 In some cases, additional uncertainty components can be applicable.

In some cases a requirement for an expanded uncertainty of a REFERENCE TEMPERATURE SOURCE can be more severe than 0,07 °C. An example is an accuracy requirement for a basal CLINICAL THERMOMETER, which is 0,1 °C. In this case the U_{RTS} should be of the order of 0,03 °C. Accordingly, the uncertainty components U_{RT}, U_{stab} and U_{hom} need to be smaller.

Annex CC
(informative)

Environmental aspects

The environmental impact generated by a CLINICAL THERMOMETER measuring the temperature of PATIENTS is mainly isolated to the following occurrences:

1) impact at local environment during operation, including routine inspection and adjustments by the user, according to the ACCOMPANYING DOCUMENT or routine procedures;

2) use, cleaning and disposal of consumables during operation, including routine inspection and adjustments by the user, according to the ACCOMPANYING DOCUMENT or routine procedures;

3) scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the CLINICAL THERMOMETER.

Table CC.101 contains a mapping of the life cycle of CLINICAL THERMOMETERS to aspects of the environment.

Table CC.101 — Environmental aspects addressed by clauses of this standard

Environmental aspects (Inputs and Outputs)		Product Life Cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	1.3	1.3	1.3	1.3
2	Energy consumption	1.3	1.3	1.3	1.3
3	Emission to air	1.3	1.3	1.3	1.3, 7.5
4	Emission to water	1.3	1.3	1.3	1.3, 7.5
5	Waste	1.3	1.3	1.3	1.3, 7.5
6	Noise	1.3	1.3	1.3	1.3
7	Migration of hazardous substances	1.3	1.3	1.3	1.3, 7.5
8	Impacts on soil	1.3	1.3	1.3	1.3, 7.5
9	Risks to the environment from accidents or misuse	1.3	1.3	1.3	1.3

Annex DD
(informative)

Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142

This standard has been prepared to support the essential principles of safety and performance of CLINICAL THERMOMETERS as medical devices in accordance with ISO/TR 16142:2006. This standard is intended to be acceptable for conformity assessment purposes.

Compliance with this standard provides one means of demonstrating conformity with specific essential principles of ISO/TR 16142:2006. Other means are possible.

Table DD.101 contains a mapping of the clauses and subclauses of this standard to essential principles of ISO/TR 16142:2006.

Table DD.101 — Correspondence between this standard and the Essential Principles

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.1, A.2, A.3	All	And via IEC 60601-1
A.4	201.4, 201.7, 201.15, 201.101, 201.103	And via IEC 60601-1, Clauses 4, 7, and 15
A.5	201.4, 201.7, 201.7.2.1.101 f), 201.15, 201.16, 201.101, 201.103	And via IEC 60601-1, Clauses 4, 7, 15 and 16
A.6	201.4.2, 201.103	And via IEC 60601-1, Subclause 4.2
A.7.1	201.9, 201.11, 201.15, 201.103	And via IEC 60601-1, Clauses 9, 11, 15
A.7.2	201.11, 201.15, 201.16	And via IEC 60601-1, Clauses 11, 15, 16
A.7.3	201.4, 201.11	And via IEC 60601-1, Clauses 4, 11
A.7.4	—	Not applicable
A.7.5	201.7.9.2.14.101, 201.11, 201.13	And via IEC 60601-1, Clause 11, 13
A.7.6	201.11, 201.13, 201.103	And via IEC 60601-1, Clause 11, 13
A.8.1	201.11, 201.16	And via IEC 60601-1, Clauses 11, 16
A.8.1.1, A.8.1.2	—	Not applicable
A.8.2, A.8.3	201.11	And via IEC 60601-1, Clause 11
A.8.4	201.11, 201.103	And via IEC 60601-1, Clause 11
A.8.5	201.11	And via IEC 60601-1, Clause 11
A.8.6	201.7, 201.7.2.1.101 c), 201.7.2.101.1 d), 201.7.2.101.1 f), 201.11	And via IEC 60601-1, Clause 11
A.8.7	201.7, 201.7.2.1.101 c), 201.7.2.1.101 f)	And via IEC 60601-1, Clause 7
A.9.1	201.4, 201.8, 201.9, 201.11, 201.14, 201.16, 201.103	And via 60601-1, Clauses 4, 8, 9, 11, 14, 15, 16 and Subclause 7.9
A.9.2	201.4, 201.4.2, 201.4.3, 201.5, 201.8, 201.9, 201.12, 201.15, 201.103	And via IEC 60601-1, Clauses 4, 5, 8, 9, 12, 15 and Subclauses 4.2, 7.9
A.9.3	201.4, 201.8, 201.11, 201.13, 201.15	And via IEC 60601-1, Clauses 4, 8, 11, 15 and Subclauses 7.9, 13.1.2, 13.2.6
A.10.1	201.4, 201.4.3, 201.12.1, 201.101.2, 201.103	And via IEC 60601-1, Clauses 4, 15 and Subclauses 7.9, 12.1

Table DD.101 *(continued)*

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.10.2	201.4, 201.12	And via IEC 60601-1, Clauses 4, 12, 15 and Subclause 7.9
A.10.3	201.7, 201.7.2.101 a), 201.7.4.3.101	And via IEC 60601-1, Clause 7
A.11.1	201.4, 201.10, 201.12, 201.17, 201.103, 202	And via IEC 60601-1, Clauses 4, 10, 12, 15, 17 and Subclause 7.9
A.11.2.1	201.4, 201.10, 201.12	And via IEC 60601-1, Clauses 4, 10, 12, 15 and Subclause 7.9
A.11.2.2	201.4, 201.12, 201.103	And via IEC 60601-1, Clauses 4, 12, 15 and Subclause 7.9
A.11.3	201.4, 201.10, 201.12	And via IEC 60601-1, Clauses 4, 10, 12, 15 and Subclause 7.9
A.11.4	201.4, 201.7	And via IEC 60601-1, Clauses 4, 7, 15 and Subclause 7.9
A.11.5.1, A.11.5.2, A.11.5.3	201.4, 201.10, 201.12	And via IEC 60601-1, Clauses 4, 10, 12, 15 and Subclause 7.9
A.12.1	201.4, 201.14	And via IEC 60601-1, Clauses 4, 14
A.12.2	—	Not applicable
A.12.3, A.12.4	201.4, 201.7, 201.12	And via IEC 60601-1, Clauses 4, 7, 12
A.12.5	201.4, 201.17, 201.103, 202	And via IEC 60601-1, Clauses 4, 17
A.12.6	201.4, 201.8	And via IEC 60601-1, Clauses 4, 8
A.12.6.1	201.4, 201.8, 201.103	And via IEC 60601-1, Clauses 4, 8
A.12.7.1	201.4, 201.9, 201.15, 201.103	And via IEC 60601-1, Clauses 4, 9, 15
A.12.7.2	201.4	And via IEC 60601-1, Clauses 4
A.12.7.3	201.4, 201.9	And via IEC 60601-1, Clauses 4, 9
A.12.7.4	201.4, 201.8	And via IEC 60601-1, Clauses 4, 8
A.12.7.5	201.4, 201.8, 201.11, 201.15, 201.16, 201.103	And via IEC 60601-1, Clauses 4, 8, 11, 15, 16
A.12.8.1	201.4, 201.12	And via IEC 60601-1, Clauses 4, 12
A.12.8.2, A.12.8.3	201.4, 201.7, 201.12	And via IEC 60601-1, Clauses 4, 7, 12
A.13.1	201.7, 201.16, 201.103	And via IEC 60601-1, Clauses 7, 16
A.14.1	201.4, 201.11, 201.102, 201.103	And via IEC 60601-1, Clauses 4, 11

Bibliography

[1] ISO/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[2] ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

[3] ASTM E1965-98, *Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature*

[4] EN 12470-5:2003, *Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device)*

[5] JIS T4207:2005, *Infrared ear thermometers*

[6] Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff, July 6, 2001, available in the internet URL: http://www.fda.gov/cdrh/ohip/guidance/1333.pdf

[7] Guidance for Industry and FDA Reviewers — Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, January 3, 2000, available in the internet URL: http://www.fda.gov/cdrh/ode/397.pdf

[8] Guidance for Industry and FDA Staff — Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices, May 1, 2006, available in the internet URL: http://www.fda.gov/cdrh/comp/guidance/1217.pdf

[9] Guidance for Industry and FDA Staff — Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices, September 25, 2006, available in the internet URL: http://www.fda.gov/cdrh/ode/guidance/1216.pdf

[10] Guidance for Industry and FDA Staff — Premarket Assessment of Pediatric Medical Devices, available in the internet URL: http://www.fdgov/cdrh/mdufma/guidance/1220.pdf

[11] ANBAR, R.D., et al., Difficulties in universal application of criteria identifying infants at low risk for serious bacterial infection. *J. Pediatr.* 1986, **109**, p. 483

[12] BACHUR, R, et al., Bacteremia and meningitis among infants with urinary tract infections. *Pediatr. Emerg. Care.* 1995, **11**, p. 280

[13] BAKER, M.D., et al., Outpatient management without antibiotics of fever in selected infants. *N. Engl. J. Med.* 1993, **329**, p. 1437

[14] BAKER, M.D., et al., Unpredictability of serious bacterial illness in febrile infants from birth to 1 month of age. *Arch. Pediatr. Adolesc. Med.* 1999, **153**, p. 508

[15] BARAFF, L.J. Management of the febrile child: a survey of pediatric and emergency medicine residency directors. *Pediatr. Infect. Dis. J.* 1991, **10**, p. 795

[16] BARAFF, L.J. et al. Practice guideline for the management of infants and children 0 to 36 months of age with fever without source. Agency for Health Care Policy and Research. *Ann. Emerg. Med.* 1993, **22**, p. 1198

[17] BARAFF, L.J. Management of fever without source in infants and children. *Ann. Emerg. Med.* 2000, **36**, p. 602

[18] BARTON, S.J. et al. Pediatric temperature measurement and child/parent/nurse preference using three temperature measurement instruments. *J. Pediatr. Nurs*. 2003, **18**, pp. 314-320

[19] BASKIN, M.N. The prevalence of serious bacterial infections by age in febrile infants during the first 3 months of life. *Pediatr. Ann*. 1993, **22**, p. 462

[20] BASKIN, M., et al. Outpatient treatment of febrile infants 28-89 days of age with intramuscular administration of ceftriaxone. *J. Pediatr*. 1992, **120**, pp. 22-27

[21] BENZINGER, M. Tympanic thermometry in anesthesia and surgery. *JAMA* 1969, **209**, pp. 1207-1211

[22] BOIVIN, W., et al. Measurement of radiofrequency electromagnetic fields in and around ambulances. *Biom. Instrum. Tech.* 1997, **31**(2), pp. 145-154

[23] BONADIO, W. Evaluation and management of serious bacterial infections in the febrile young infant. *Pediatr. Infect. Dis. J*. 1990, **9**(12), pp. 905-912

[24] BRINNEL, H., et al. Tympanic temperature is a core temperature in humans. *J. Therm. Biol.* (UK) 1989, **14**, pp. 47-53

[25] CHENG, T.L., et al. Effect of bundling and high environmental temperature on neonatal body temperature. *Pediatrics* 1993, **92**, p. 238

[26] CHILDS, C., et al. Tympanic membrane temperature as a measure of core temperature. *Arch. Dis. Child* 1999, **80**, pp. 262-266

[27] CRAIG, J.V., et al. Infrared ear thermometry compared with rectal thermometry in children: a systematic review. *Lancet* 2002, **360**, pp. 603-609

[28] DAANEN, H. Infrared tympanic temperature and ear canal morphology. *J. Med. Eng. Technol.* 2006, **30**, pp. 224-234

[29] DAGAN, R., et al. Ambulatory care of febrile infants younger than 2 months of age classified as being at low risk for having serious bacterial infections. *J. Pediatr*. 1988, **112**, p. 355

[30] ERICKSON, R.S., et al. Accuracy of infrared ear thermometry and other temperature methods in adults. *Am. J. Crit. Care* 1994, **3**, pp. 40-54

[31] FRADEN, J., et al. U.S. Patent No. 5163418. *Speculum cove*r (1992-11-17)

[32] FRADEN, J. Medical infrared thermometry: Review of modern techniques. In: Temperature. Its measurement and control in science and industry. *Am. Inst. Phys.* 1992, **6**(2), pp. 825-830

[33] FRADEN, J. *Handbook of modern sensors*, 3rd. ed. Springer, 2004

[34] FRADEN, J. U.S. Patent No. 6447160, *Blackbody cavity for calibration of infrared thermometers* (2002-09-10)

[35] FOWLER, J.B. A third generation water bath based blackbody source. *J. Res. Nat. Inst. Stand. Technol.* 1995, **100**, pp. 591-599

[36] GROVER, G., et al. The effects of bundling on infant temperature. *Pediatrics* 1994, **94**, p. 669

[37] HAY, D., et al. The use of infrared thermometry for the detection of fever. *Br. J. Gen. Pract*. 2004, **54**, pp. 48-50

[38] HOUDAS, Y., et al. *Human body temperature*. Plenum, New York, NY, 1982

[39] IKEDA, M., et al. U.S. Patent No. 5066141, *Electronic clinical thermometer* (1991-11-19)

[40] KADISH, H.A. et al. Applying outpatient protocols in febrile infants 1-28 days of age: can the threshold be lowered? *Clin. Pediatr*. 2000, **39**, p. 81

[41] LANHAM, D., et al. Accuracy of tympanic temperature readings in children under 6 years of age. *Pediatr. Nurs.* 1999, **251**, pp. 39-42

[42] MCCARTHY, P.W., et al. The vagaries of ear temperature assessment. *J. Med. Eng. Technol*. 2006, **30**, pp. 242-251

[43] PANTELL, R.H. et al. Management and outcomes of care of fever in early infancy. *JAMA* 2004, **291**, p. 203

[44] PUSNIK, I., et al. Infrared ear thermometers—parameters influencing their reading and accuracy. *Physiol. Meas*. 2005, **26**, pp. 1075–1084

[45] PUSNIK, I. et al. IR ear thermometers: what do they measure and how do they comply with the EU technical regulation? *Physiol. Meas.* 2004, **25**, pp. 699–708

[46] PUSNIK, I. et al., Bilateral comparison of blackbody cavities for calibration of infrared ear thermometers between NPL and FE/LMK. *Physiol. Meas.* 2004, **25**, pp. 1239–1247

[47] SMITHERMAN, H.F., et al. Definition and etiology of fever in neonates and infants (less than 3 months of age). *UpToDate(R)* 2006, **13**(3), 9-7-2006

[48] SOMMER, K.D., et al. Role of measurement uncertainty in deciding conformance in legal metrology. *OIML Bull.* 2002, **XLIII**(2), pp. 19-24

[49] TORREY, S., et al. Incidence of salmonella bacteremia in infants with salmonella gastroenteritis. *J. Pediatr*. 1986, **108**, p. 718

[50] WATSON, R.S., et al. Scope and epidemiology of pediatric sepsis. *Pediatr. Crit. Care. Med*. 2005, **6**(S3), pp. 3-5

[51] WILLIAMS, C., et al. Immunology of the fetus and newborn. In: TAEUSH, H, BALLARD, R, GLEASON, C (Eds), *Avery's diseases of the newborn*, 8th ed, p. 447. Elsevier Saunders Philadelphia, PA, 2005

[52] YETMAN, R.J., et al. Comparison of temperature measurements by an aural infrared thermometer with measurements by traditional rectal and axillary techniques. *J. Pediatr*. 1993, **122**, pp. 769-773

[53] IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

Alphabetized index of defined terms used in this particular standard

ACCESSORY ..... IEC 60601-1:2005, definition 3.3
ACCOMPANYING DOCUMENT ..... IEC 60601-1:2005, definition 3.4
ADJUSTED MODE 3.1
ALARM SYSTEM ..... IEC 60601-1-8:2006, definition 3.11
APPLIED PART ..... IEC 60601-1:2005, definition 3.8
BASIC SAFETY ..... IEC 60601-1:2005, definition 3.10
BLACKBODY 3.2
CLEARLY LEGIBLE ..... IEC 60601-1:2005, definition 3.15
CLINICAL ACCURACY 3.3
CLINICAL BIAS [Δ_{cb}] 3.4
CLINICAL REPEATABILITY [σ_r] 3.5
CLINICAL THERMOMETER 3.6
DIRECT MODE 3.7
ESSENTIAL PERFORMANCE ..... IEC 60601-1:2005, definition 3.27
EXPECTED SERVICE LIFE ..... IEC 60601-1:2005, definition 3.28
EXTENDED OUTPUT RANGE 3.8
FLUID BATH 3.9
HAND-HELD ..... IEC 60601-1:2005, definition 3.37
HAZARD ..... IEC 60601-1:2005, definition 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005, definition 3.40
IMMUNITY TEST LEVEL ..... IEC 60601-1-2:2007, definition 3.15
INTERNAL ELECTRICAL POWER SOURCE ..... IEC 60601-1:2005, definition 3.45
LABORATORY ACCURACY 3.10
LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM ..... IEC 60601-1-2:2007, definition 3.18
LIMITS OF AGREEMENT (L_A) 3.11
MANUFACTURER ..... IEC 60601-1:2005, definition 3.55
MEASURING SITE 3.12
ME EQUIPMENT (MEDICAL ELECTRICAL EQUIPMENT) ..... IEC 60601-1:2005, definition 3.63
ME SYSTEM (MEDICAL ELECTRICAL SYSTEM) ..... IEC 60601-1:2005, definition 3.64
MODEL OR TYPE REFERENCE ..... IEC 60601-1:2005, definition 3.66
NORMAL USE ..... IEC 60601-1:2005, definition 3.71
OPERATING MODE 3.13
OPERATOR ..... IEC 60601-1:2005, definition 3.73
OUTPUT RANGE 3.14
OUTPUT TEMPERATURE 3.15
PATIENT ..... IEC 60601-1:2005, definition 3.76

PORTABLE ..... IEC 60601-1:2005, definition 3.85
PROBE 3.16
PROBE CABLE EXTENDER 3.17
PROBE COVER 3.18
PROCESS ..... IEC 60601-1:2005, definition 3.89
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ..... IEC 60601-1:2005, definition 3.90
RATED (value) ..... IEC 60601-1:2005, definition 3.97
REFERENCE BODY SITE 3.19
REFERENCE CLINICAL THERMOMETER (RCT) 3.20
REFERENCE TEMPERATURE SOURCE 3.21
REFERENCE THERMOMETER 3.22
REPROCESSING (REPROCESSED) 3.23
RESIDUAL RISK ..... IEC 60601-1:2005, definition 3.100
RISK ..... IEC 60601-1:2005, definition 3.102
RISK CONTROL ..... IEC 60601-1:2005, definition 3.105
RISK MANAGEMENT ..... IEC 60601-1:2005, definition 3.107
RISK MANAGEMENT FILE ..... IEC 60601-1:2005, definition 3.108
SENSOR 3.24
STATIONARY ..... IEC 60601-1:2005, definition 3.118
TECHNICAL ALARM CONDITION ..... IEC 60601-1-8:2006, definition 3.36
TEST MODE 3.25
USABILITY ..... IEC 60601-1-6:2006, definition 3.11
USABILITY ENGINEERING FILE ..... IEC 60601-1-6:2006, definition 3.13
VALIDATION (VALIDATED) ..... IEC 60601-1-6:2006, definition 3.26
VERIFICATION (VERIFIED) ..... IEC 60601-1:2005, definition 3.138

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™